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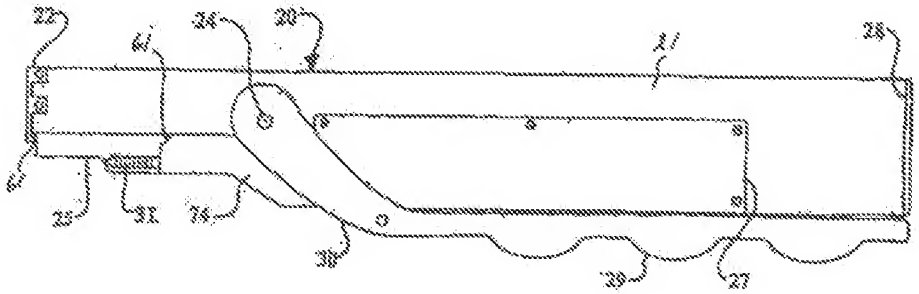
(54) Title: NEEDLE FREE HYPODERMIC INJECTOR AND AMPULE FOR INTRADERMAL, SUBCUTANEOUS AND INTRAMUSCULAR INJECTION



(57) Abstract: A needle free hypodermic injector comprising a hand manipulatable elongate housing, an impact impulse injection mechanism within the housing, a suction generating means within the housing and cooperable with the impact impulse injection mechanism, a safety interlock mechanism, at least one medicament containing ampule cooperable with the impact impulse injection mechanism and the suction generating means and having a jet orifice through which medicament is injectable through a skin surface in response to an impulse placed on the medicament by the impact impulse injection mechanism, and means to receive and hold the ampule on the injector in registration with the impact impulse injection mechanism and in communication with the suction generating means; whereby the injector is adapted to expel the medicament from the ampule in a jet stream of sufficient velocity to penetrate skin tissue held against the orifice by the suction generating means and to deposit the medicament intradermally, subcutaneously or intramuscularly based on the position and angle of the jet orifice.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

NEEDLE FREE HYPODERMIC INJECTOR AND AMPULE FOR INTRADERMAL, SUBCUTANEOUS AND INTRAMUSCULAR INJECTION

FIELD OF THE INVENTION

This invention relates to a needle free, impact impulse injector device and disposable, single use, fillable or pre-filled, ampules therefor that are capable of delivering intradermal, (ID), subcutaneous (SUB-Q) and intramuscular (IM) injections in human or animal tissue by means of a thin high pressure liquid jet stream of sufficient velocity to penetrate the tissue of the recipient. The injector deposits medicament intradermally, or subcutaneously, or intramuscularly, utilizing the single use, disposable, medicament ampules that are designed to provide interfaces to the activation device, allowing easy installation by hand or mechanically from a multiple ampule dispensing apparatus, and providing exact positioning and sealing to the activation device structure. The ampules further contain features that induce a vacuum to stretch the skin, keeping the skin precisely aligned with the jet orifice for the short duration of the injection. The ampule's orifice has different offset variations for ID, SUB-Q or IM injections. Ampules and injectors may also be adjusted for variations in medicament viscosity as required by various classes of medicaments including providing multiple orifices in the ampule for injection of larger doses or wider patterns. The injector device is manually, pneumatically and/or electrically or electromagnetically activated and provides interface features for mounting the ampules, and features rendering it possible for the impulse force to inject the medicament at any angle from horizontal to vertical relative to the skin surface as well as at skew angles, as the activation process is performed. In addition, the activation device provides safety interlock features which prevent the impulse force from being inadvertently activated, except when the ampule is properly interfaced with the skin surface. The injector provides the operator with a comfortable, light weight device that allows the operator to quickly and easily load an ampule, properly position the ampule on the skin surface, activate the impulse force, inject the medicament and reset the activation device.

BACKGROUND OF THE INVENTION

In this invention, a needle-free ampule is provided which discharges a pre-measured

quantity of fluid medicament in a thin jet at a sufficient velocity to penetrate the tissue of both humans and animals to be treated or vaccinated at any angle from horizontal to vertical.

This invention utilizes a single-use, disposable medicament ampule having the capability to apply a vacuum to stretch and properly hold the skin prior to injecting a medicament into the tissue, and a manually, pneumatically, electrically or electromagnetically operated activation injector device. The ampule and the injector are truly unique designs constructed with materials presently being used in the medical industry and designed to minimize effort, be easy to handle and operate. The size and shape selected also minimize weight. The age, size of hands, hand strength, skin type and thickness, as well as visibility of operations, were very important considerations.

Present state of the art attempts to inject medications intradermally have met with only limited success due to the inherent difficulty associated with accurate positioning of the skin relative to the injector jet opening and the lack of precise control of the jet pressure vs. skin penetration when the injection is performed normal to the skin surface. In addition, present systems lack precise control and repeatability of the injection jet velocity due to mechanical equipment tolerance variations within the pressure/force generators utilized. Some present devices present safety concerns due to the lack of safety interlocks to prevent the device from being activated when not in proper contact with the skin, and catastrophic failures have been observed in the injector bodies in part caused by the lack of pressure control inherent in the device designs.

Of particular interest is the ability to deliver medicament to Langerhans cells within the skin. Langerhans cells are dendritic cells generally located in the upper spinosum layer of the skin. These cells are known to participate in cutaneous immune responses and migrate from the skin to the lymph nodes. They possess surface receptors common to macrophages and function as antigen presenting cells to T and B lymphocytes. The Langerhans cells serve to fix and process cutaneous antigens and, as such, are the first immune cells to arrive at sites of inflammation. For this reason, Langerhans cells are of particular interest in immune system studies with respect to enhancing vaccine development and creating treatments for auto-immune diseases and anti-rejection therapies.

Needleless injectors have been used as an alternative to hypodermic needle type injectors for delivering drugs, vaccines, local anaesthetics and other fluids into the human or animal tissue. The medicament is discharged at high velocity so as to first penetrate the epidermis and thereafter be deposited in the tissues of the subject. An alternative method is to press the discharge nozzle onto the skin and force the fluid at very high pressure through the epidermis. Such prior art devices result in substandard and painful injections because of this blasting action and the inability to address the variables of flow control once the skin is penetrated. They are also deficient with respect to being able to provide the force necessary to penetrate the stratum corneum while restricting medicament delivery to the intradermal area generally and, specifically, the upper layers of the skin.

Prior art devices generally employ spring loaded piston pumps to withdraw fluid from a reservoir. At the end of the piston retracting stroke, the piston is disengaged from the retracting mechanism and reverses direction to pressurize the fluid for ejection from the delivery nozzle. In some devices the fluid is contained in an adjacent container or vessel within the device and the fluid is fed into the nozzle under pressure and discharged under pressure through the delivery nozzle. In other prior art devices the piston is driven on the discharge stroke by gas or an electric motor instead of a spring. In most of these devices the discharge orifice must be placed firmly on the skin to make direct contact of the nozzle with the epidermis. To achieve suitable contact, the orifice is pressed firmly into the epidermis by the operator at an angle that is normal to the skin surface, usually perpendicular to the plane of the skin, so as to stretch the epidermis at the point of contact and thereby increase the ability of the injection to penetrate the stretched tissue at the point of contact. However, the pressing of the orifice into the epidermis is a variable that is dependent on the device's operator and the ability of the recipients to tolerate the device being pressed against their anatomy.

Typically, the use of existing devices results in loss of medicament at the nozzle entry point, poor injections on account of the recipient's movements or the operator's inexperience and receipt of the injection at an angle that either does not penetrate or penetrates too much for placement and dispersal of the medicament at the correct depth and layer of tissue. In

addition, premature operations are common, as well as relative movement between the epidermis and orifice which can cause tearing of the skin during injection, resulting in pain and poor transfer of the medicament to the recipient. In other instances, the epidermis will deform away from the orifice and the injection fluid will leak away from the point of entry. At other times, the devices attempt to stretch the epidermis by deforming over the discharge orifice. In all of these conditions, the success of the injection procedure depends and rests on the ability of the operator to consistently perform, using the device to get an acceptable discharge and penetration of the epidermis.

Various methods have been proposed to overcome these problems such as powered injectors, sensing and control devices to enhance their performance, including compressed gas cylinder and electrical injectors, which are often heavy and unwieldy and encumbered with variations in gas supply, pressure, leakage.

The need for medicament supply and personnel skill have produced problems for using these devices, for example, precisely measuring and controlling of the quantity of medicament administered and ensuring that the injector delivers the correct amount of medicament into the proper tissue. The following patents have attempted to address these known problems, with varying degrees of success, and proposed some methods as follows:

US Patent #3,859,996, Mizzy, discloses a controlled leak method to ensure that the injector orifice is placed correctly at the required pressure on the subject's skin and at the correct attitude to the skin. When placement conditions are met, controlled leak is sealed off by contact pressure on the subject's skin and the pressure within the injector control circuit rises until a pressure sensitive pilot valve opens to admit high pressure gas to drive the piston and inject the medicament. This use of valving and pressure gas renders the device complex to manufacture and use and does not apply to the present invention.

WO Patent 82/02835, Cohen and Ep-A-347190, Finger, disclose a method to improve the seal between the orifice and the skin and prevent relative movement between each. This method is to employ a vacuum device to suck the epidermis directly and firmly onto the discharge orifice. The discharge orifice is positioned normal to the skin surface in order to suck the epidermis into the orifice. This method for injection of the medicament into the skin

and the injector mechanism are different and do not apply to the present invention because of its unique ampule design.

US Patent #3,859,996, Mizzy, further discloses a pressure sensitive sleeve on the injector which is placed on the subject and whereby operation of the injector is prevented from operating until the correct contact pressure between orifice and the skin is achieved. The basic aim is to stretch the epidermis over the discharge orifice and apply the pressurized medicament at a rate which is higher than the rate at which the epidermis will deform away from the orifice. This method of stretching the skin on to the orifice, together with the arrangements of the mechanism are totally different from the present invention and, consequently, do not apply.

US Patent #5,480,381, T. Weston, discloses a means of pressuring the medicament at a sufficiently high rate to pierce the epidermis before it has time to deform away from the orifice. In addition, the device directly senses that the pressure of the discharge orifice on the subject's epidermis is at a predetermined value to permit operation of the injector. The device is based on a cam and cam follower mechanism for mechanical sequencing, and contains a chamber provided with a liquid outlet for expelling the liquid, and an impact member, to dispell the liquid. The sequencing and cam operation are driven by an electric motor gear-box, and along with the cam action sequencing and adjustable pressure sensing do not apply to the present invention.

US Patent #5,891,086, T. Weston, describes a needleless injector that contains a chamber that is pre-filled with a pressurized gas which exerts a constant force on an impact member in order to strike components of a cartridge and expell a dose of medicament. This device contains an adjustment knob which sets the dose and the impact gap, and uses direct contact pressure sensing to initiate the injection. This use of contact pressure sensing, the need for constant adjustment and the use of pressurized gas to implement the injection process do not apply to the present invention.

BRIEF SUMMARY OF THE INVENTION

The subject of the present invention represents an innovative approach to hypodermic

needle-free injections, either Intradermal (ID), Subcutaneous (SUB-Q) or Intramuscular (IM), providing a process and a mechanization which contains disposable filled or prefilled medicament ampules and a manuallyor automatically operated activation device. There are many advantages covered by this invention. Above all, the injection uses horizontal impact impulse jet pressure, and thus it spreads the particles over a larger area than using a needle syringe, decreases the local pressure in the tissue, and eliminates leakage of the fluid from the opening in the tissue thereby reducing the possibility of spreading infectious. The apparatus is capable of injection at any angle between horizontal and vertical in addition to laterally relative to the center line of the ampule, depending on the specific conditions of the medicament, injection site, etc. A unique feature of this invention is that the medicament is driven out of the ampule that holds it with a known and controlled impact impulse force.

A further innovation of the present invention is the process of the stretching of the skin, which increases permeability thus reducing the amount of energy required to inject fluid into a tissue, in conjunction with the injecting of the fluid horizontally to vertically and/or laterally into the skin which allows controlled positioning of the tissue for intradermal, subcutaneous or intramuscular injections. Also significant is the introduction of a safety feature built into the injector that will not allow operation until the skin is properly positioned.

The ampule interfaces with the injector allowing installation by hand or mechanical means, and has features for the application a vacuum produced by the operation of the injector that stretches and properly holds the skin, precisely aligned with the jet orifice during the short duration of the injection. The activation device provides the interface for mounting the ampule and for delivering the impact impulse force required to inject the medicament as the activation process is performed. Each ampule body includes a see through window with external gradient markers to indicate the quantity of medicament the ampule contains.

In a second embodiment of this invention, the injector operates in like manner as the primary embodiment, with the exception that certain functions and sequence operating components utilize external air pressure for activation. The handle has been replaced with a finger operated trigger, and return functions are all air driven. Alternatively, the pneumatic

operation can be achieved using an electronic solenoid with power provided by a battery pack that may be part of or separate from the injector. The ampule configuration in both embodiments is identical and its attachment to the injector and filling procedure are the same. Inasmuch as each injector embodiment utilizes the same ampule, then each provides a means for administering either Intradermal (ID), Subcutaneous (SUB-Q) or Intramuscular (IM) injections.

A still further embodiment of the present invention provides an injector that is adapted to receive a multiple ampule assembly and a multiple ampule assembly therefor. The components and operation of the injector are substantially identical to those of the other embodiments except that the front end of the injector is modified to receive a rotatable, multiple ampule assembly, which assembly has a plurality of ampules arranged in a cylindrical cartridge. The cartridge is rotatable on the forward end of the injector so as to bring each ampule thereof into registration with the suction and injection means of the injector.

Present state of the art attempts to inject medications intradermally have met with only limited success due to the inherent difficulty associated with accurate positioning of the skin relative to the injector jet opening and the lack of precise control of the jet pressure versus skin penetration when the injection is performed normal to the skin surface. In addition, present systems lack precise control and repeatability of the injection jet velocity due to mechanical equipment tolerance variations within the pressure/force generators utilized. Some present devices indicate safety concerns due to the lack of safety interlocks to prevent the device from being accidentally activated when not in proper contact with the skin, and observed catastrophic failures in the injector bodies in part caused by the lack of precise pressure control inherent in the device designs.

The present invention overcomes these deficiencies by the combination of the injector device and the ampule used therewith. The ampule is a key element of the system as it is the part which holds the medicament to be injected and interfaces with both the injector and the patient's skin surface to apply the suction generated by the injector in order to draw the skin tight for proper injection. The ampule further interfaces with the injector to provide proper

functioning of the safety interlock since release of the interlock requires establishing a full suction on the system which cannot be achieved without the ampule. With the ampule and the injector combination of the present invention it is now possible to achieve needle-less injection of medicament intradermally, subcutaneously and intramuscularly at any angle relative to the skin surface. Furthermore, the ampule and injector combination of the present invention are capable of achieving the shallow intradermal injection necessary to accurately and reliably deliver medicament to the Langerhans cells in the upper spinosum layer of the skin.

Thus, the present invention provides a needle free hypodermic injector comprising a hand manipulatable elongate housing, an impact impulse injection mechanism within the housing, a suction generating means within the housing and cooperable with the impact impulse injection mechanism, a safety interlock mechanism, at least one medicament containing ampule cooperable with the impact impulse injection mechanism and the suction generating means and having a jet orifice through which medicament is injectable through a skin surface in response to an impulse placed on the medicament by the impact impulse injection mechanism, and means to receive and hold the ampule on the injector in registration with the impact impulse injection mechanism and in communication with the suction generating means; whereby the injector is adapted to expel the medicament from the ampule in a jet stream of sufficient velocity to penetrate skin tissue held against the orifice by the suction generating means and to deposit the medicament intradermally, subcutaneously or intramuscularly based on the position and angle of the jet orifice.

The present invention further provides an ampule for a needle free hypodermic injector, wherein the ampule comprises an elongated body having a forward end, a rearward end, a substantially planar upper surface and a lower surface having a downward offset between the forward end and the rearward end, this offset providing a forward facing step face, a horizontally disposed bore within the body extending from the rearward end of the body to a point substantially adjacent to the step face, the bore being open at the rearward end and having a sealing plunger disposed therein to be driven by the impact impulse mechanism, the bore further having a jet orifice extending through the step face, whereby the bore is

capable of holding a quantity of medicament injectable through a skin surface held against the orifice in response to the plunger being driven forward in the bore by the impact impulse injection mechanism.

The present invention still further provides a needle free hypodermic injector wherein the ampule further comprises at least one suction port extending vertically through the body from the upper surface to the lower surface at a point forward of the step face, the suction port being in fluid communication with the suction generating means whereby a suction generated by the suction generating means is applicable to the skin surface through the port to draw the skin surface upward against the lower surface of the ampule and the jet orifice prior to injection thereby stretching the skin to improve its porosity to the jet of medicament and, depending on the angle and placement of the orifice, to direct the jet of medicament intradermally, subcutaneously or intramuscularly.

The present invention still further provides a needle free hypodermic injector comprising an injector assembly and at least one medicament containing ampule removably attachable to the injector assembly, the injector assembly comprising an elongated hand manipulatable housing, the housing comprising a main body portion containing a mechanical impact impulse means comprising a drive rod linearly reciprocatable within the housing between a cocked position and an injection position, a compressible drive spring linearly concentric about a rear portion of the drive rod, the spring being confined between a stationary abutment within the housing and a projection substantially midway along the drive rod whereby rearward displacement of the drive rod compresses the spring, a latch mechanism cooperating with the projection to releasably hold the drive rod in a cocked position wherein the spring is compressed, a release means to release the latch mechanism when injection is desired, and a cocking means cooperating with the drive rod and operable to draw the drive rod in a rearward direction to the cocked position thereby compressing the spring and engaging the latch mechanism. The injector further comprises a forward nose portion adapted to removably receive at least one ampule and having detent means to releasably secure the ampule to the injector assembly when the impact impulse mechanism is in the cocked position, the at least one ampule comprising a body having a forward end and a

rearward end, a substantially planar upper surface and a stepped lower surface having a forward facing step face therein, the body having formed therein behind the step face a horizontally disposed substantially cylindrical medicament chamber open at the rearward end and narrowing to a jet orifice in the step face, the chamber being sized and positioned to receive a forward end of the drive rod when the ampule is secured to the injector assembly and the latch mechanism is released, the chamber further containing a sealing plunger providing a means to retain medicament in the chamber, the plunger adapted to be engaged by the drive rod upon release of the latch mechanism, whereby the drive rod drives the plunger forward within the horizontally disposed chamber forcing the medicament under pressure through the jet orifice for injection into a skin surface held against the ampule.

The needle free hypodermic injector of the present invention further comprises at least one suction port vertically disposed through the ampule body forward of the jet orifice, a suction generating means disposed in the main body portion of the housing and suction conduits within the housing and the nose portion providing fluid communication between the suction generating means and the at least one suction port whereby suction generated by the suction generating means is conveyed to the at least one suction port of the ampule, the suction serving to draw the skin surface against the ampule and the orifice prior to injection. To improve the suction of the skin surface against the ampule and, preferably in the case of intradermal injection, to lift the skin surface slightly higher than the level of the jet orifice thereby providing an injection path to the spinosum layer of the skin, it is preferred that the lower surface of the ampule immediately surrounding the suction port be concave thereby forming a slight depression into which the skin is drawn by the suction.

Although the injector does not touch the skin tissue around the injection, it can be submerged in alcohol for sterilization, if desired, since all materials are presently being used in the medical industry, and are compatible with all current sterilization methods.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

FIG. 1 is a top view of the needle-free injector of the present invention.

FIG. 2 is a side view of the needle-free injector in a manual configuration.

FIG. 3 is a longitudinal cross section of the needle-free injector of Fig. 2 prior to injection.

FIG. 4 is a cross section of the needle-free injector of Fig. 2 after injection.

FIG. 5 is a view of the end cap of the needle-free injector of Fig. 2.

FIG. 6 is a vertical cross section through the injector of Fig. 2 at the vacuum piston.

FIG. 7 is a partial longitudinal cross section of the injector of Fig. 2 through the suction manifold.

FIG. 8 is a longitudinal cross section of an alternative embodiment of the injector configured for operation by air pressure prior to injection.

FIG. 9 is a longitudinal cross section of the alternative embodiment of the injector configured for operation by air pressure after injection.

FIG. 10A is a side view of the return piston housing of the alternative embodiment of the injector of Fig. 8.

FIG. 10B is an end view of the return piston housing of the alternative embodiment of the injector of Fig. 8.

FIG. 11 is a side view of an ampule according to the present invention.

FIG. 12 is a top view of an ampule according to the present invention .

FIG. 13 is a longitudinal cross section through the ampule of Fig. 11.

FIG. 14 is a view of an ampule in an adaptor for filing.

FIG. 15 is a top view of an alternative embodiment of an ampule according to the present invention having a stopper for filing via a hypodermic syringe.

FIG. 16 is a longitudinal cross section of the ampule of Fig. 15 with protective coverings in place.

FIG. 17 is a longitudinal cross section of the ampule of Fig. 15 being filled.

FIG. 18 is a longitudinal cross section of the ampule of Fig. 15 filled with medicament and sealed for use .

FIG. 19 is a side view of a multiple ampule unit injector.

FIG. 20 is a longitudinal cross section of the multiple ampule unit injector of Fig.19.

FIG. 21 is a detailed cross section of the forward end of the multiple ampule unit injector of Fig. 19.

FIG. 22 is a vertical cross section of the multiple ampule unit injector of Fig. 19 through the vacuum ports of the ampule assembly.

FIG. 23 is a view of the ampule assembly showing adjacent ampules.

FIG. 24 is a view showing an intradermal injection ampule in use.

FIG. 25 is a close-up view of the intradermal injection.

FIG. 26 is a view showing a subcutaneous injection ampule in use.

FIG. 27 is a close-up view of the subcutaneous injection.

LIST OF PARTS AND IDENTIFICATION NUMBERS

20 - Injector Assembly (complete)
21 - Housing
22 - Retainer Clamp
23 - Release Button
24 - Pivot (Handle)
25 - Ampule
26 - Detent
27 - Access Panel
28 - End Cap
29 - Hand Grips
30 - Handle
31 - Medicament
32 - Snap Ring
33 - Torsion Spring
34 - Seal (Large Piston)
35 - Vacuum Piston
36 - Interlock Piston Rod
37 - O-Ring
38 - Suction Port A
39 - Retainer Ring (Small Piston)
40 - Extension Link
41 - Pivot (Link)
42 - Drive Spring
43 - Drive Rod
44 - Release Catch
45 - Slide Frame
46 - Extension (Piston)
47 - Connector Link
48 - Drive Rod Latch
49 - External Air Source Fitting
50 - Ramp
51 - Roll Pins
52 - Pivot (Rod Latch)
53 - Torsion Spring (Rod Latch)

54 - Pin
55 - Release Arm
56 - Shaft
57 - Pivot (Release)
58 - Pin (Latch)
59 - Retention Ring
60 - Pivot (Slide)
61 - Locking Tabs
62 - Cylinder Bore (with dosage markers)
63 - Suction Ports
64 - Skin
65 - Ampule Plunger
66 - Outlet Orifice
67 - Ampule Body
68 - Contour
69 - Vacuum Port Plane
70 - Vacuum Port Seal
71 - Suction Tube
72 - Suction Manifold
73 - Suction Passage
74 - Insert Fairing
75 - Cushion Washer
76 - Screw
77 - Compression Spring
78 - Drive Cylinder
79 - Tooth Release Catch
80 - Interlock Hole
81 - O-Ring
82 - Connecting Rod
83 - Return Piston
84 - O-Ring
85 - Compression Spring
86 - Retention Screws
87 - Actuation Frame
88 - Pin
89 - Trigger Assembly
90 - Push Rod
91 - Pressure Ports
92 - O-Ring
93 - Plug
94 - Spring Retention Cap
95 - Support Fitting
96 - O-Ring
97 - Pressure Bleed
98 - Spring Retention Plug
99 - Compression Spring
100 - Valve
101 - O-Ring
102 - Extension Housing
103 - Luer Adaptor

104 - Rubber Seal
105 - Bushing
106 - Stopper
107 - Pull-off Protection Shield (upper)
108 - Pull-off Protection Shield (lower)
109 - Syringe
110 - Nozzle
111 - Probe
112 - Retraction Handle
113 - Vacuum Space
114 - Flat Surface
115 - Passage
116 - Shoulder Stop
117 - Capture Pad
118 - Ampule Orifice Plug
119 - Enlarged Head
120 - Projecting Ring
121 - Protective Outer Doubler
122 - Slide Frame Groove
123 - Cylinder
124 - Annular Abutment Surface
125 - Channel
126 - Small Piston
127 - Small Cylinder
128 - Drive Spring Chamber
129 - Vacuum Ports
130 - Valve Cavity
131 - Undercut
132 - Air Passage
133 - Return Piston Pocket
134 - Retention Cap Pocket
135 - Port
136 - Ampule Nose Portion
137 - Ampule Bore Chamber Portion
138 - Offset
139 - Pocket
140 - Depression (Well)
141 - Dosage Markers
142 - Luer Connection
143 - Filling Port
200 - Multiple Ampule Assembly
201 - Housing
202 - Multiple Unit Cylinder
203 - Vacuum Ports
204 - Detent Pockets
205 - Multiple Unit Cartridge
206 - Shaft
207 - Position Detent
208 - Rotation Knob
209 - Sleeve

210 - Multiple Unit Suction Tube
211 - Suction Tube Seal
212 - Multiple Unit Ampule Plunger
213 - Annular Groove
214 - Detent
215 - Ball
216 - Spring
217 - Detent
218 - Shaft Receiving Hole
219 - Electronic Identification Code
220 - Removable Tab
221 - Window
222 - Sequential Number
223 - Capture Pin

DETAILED DESCRIPTION OF THE INVENTION

This invention relates to a device and method for a needle-less jet injection of a medicament into the skin of a human or animal from a disposable fillable or pre-filled ampule that uses a vacuum to stretch the recipient's skin in order to increase its permeability for injection and which, in turn, reduces the amount of energy required to inject the medicament into the skin tissue. The vacuum further positions the skin correctly for injection of the medicament.

The method uses the device to inject a premeasured dose of medicament by means of a high pressure jet stream of sufficient velocity to penetrate human or animal epidermis, depositing the medicament intradermally, or subcutaneously, or intramuscularly, depending on the offset and angle of the disposable ampule's orifice to the epidermis and the impact impulse force. Another novelty of the process consists in injecting the medicament horizontally, or any other desired angle, into the skin from a single use ampule, spreading the particles over a larger area than when using a needle syringe.

The method provides decreased local pressure in the skin tissue at the point of injection, thus reducing local pain, minimizing tissue damage, eliminating leakage of fluid at the injection opening, and reducing the possibility of spreading infections, while providing a safety device to prevent inadvertent triggering of the injector.

The injector assembly 20 shown in FIG. 1 comprises a molded housing 21 containing the injector mechanism that is activated by a release button 23. Activation of the injector 20

dispenses the medicament 31 contained in ampule 25 shown in FIG. 2. The ampule 25 is retained on the injector 21 by a retainer clamp 22 attached to the forward end of the injector 20 and by an insert fairing 74 on the underside of the injector 20 at the opposite end of the ampule 25. The principal embodiment of the injector 20 is manually operated and is cocked for release of the medicament by rotation of a handle 30, around a shaft 56. The handle 30 is provided with shaped hand grips 29 for ease of operation. The handle 30 rotates at handle pivot 24.

The injector housing 21 is provided with an access panel 27 and an end cap 28 for ease of assembly and service of the mechanism within the housing 21. FIG. 3 shows a cross section view of the injector 20 prior to activation of the mechanism for injection. The mechanism within the housing 21 comprises a piston 35 adapted to create a vacuum for stretching the recipient's skin at the injection site immediately prior to injection and a release mechanism to pressure drive the medicament into the skin tissue. The mechanism within the housing 21 of the injector 20 also comprises a compression drive spring 42 which provides the force that drives one end of a drive rod 43 into the ampule 25 that contains the medicament. The drive rod 43 has a retention ring 59 at the opposite end which cooperates with a means for locking the drive rod 43 with the compression drive spring 42 compressed. A projecting ring 120 substantially midway along drive rod 43 provides a surface on the drive rod 43 for the compression spring 42 to push against. The opposite end of the compression drive spring 42 abuts against an annular surface 123 at the end of drive spring chamber 128 within housing 21. To eject the medicament 31 from the ampule 25, the mechanism of the injector 20 is cocked by rotation of the handle 30 to the position of Fig. 4, which pulls slide frame 45, via extension link 40, forward so that drive rod latch 48 snares retention ring 59 on the end of drive spring drive rod 43. As the slide frame 45 is pulled forward by the link 40 attached to the handle 30, the upper surface of latch 48 slides along spring ramp 50 and is rotated downward to engage the forward surface of retention ring 59. The drive rod latch 48 is preloaded to a release position by a torsion spring 53 at the pivot point of latch 48 and side frame 45. Contact of latch 48 with spring ramp 50 pushes latch 48 downward against the torsion spring load to the locking position that captures the drive rod retention ring 59.

Spring ramp 50 is preferably retained in the housing 21 by two pins 51. The drive rod latch 48 is supported by the slide frame 45 and pivots around a pin joint 52 in the upright supports of the slide frame 45 and is retained in the slide frame with a horizontal pin 58 that also retains a connector link 47. The slide frame 45 has a horizontal lower leg that slides in and is guided by a machined-in groove 122 in the housing 21. The horizontal lower leg of side frame 45 is provided with an end termination pivot point 60 for pivoting attachment of extension link 40. The rotation of the handle 30 back to the starting position shown in Fig 3 pushes the drive rod 43 rearward and compresses the spring 42 between annular surface 123 and projecting ring 120. When handle 30 is fully rotated back to the starting position, spring 42 is fully compressed and projecting ring 120 is engaged by tooth release catch 79 which depends from the underside of release catch 44 and holds spring 42 and drive rod 43 in a compressed position ready for release to drive the medicament 31 out of the ampule 25 with the drive rod 43. To achieve this movement of the slide frame 45 with the link 40 that is attached to both slide frame 45 and handle 30, the link 40 rotates around pivot 41 on the handle and pivot 60 on the slide frame.

The handle 30 itself is attached to the injector assembly housing 21 and rotates around the pivot 24. The injector handle 30 attached to the outside of the housing 21 comprises two contoured legs that straddle the housing 21 with and each leg being attached to the pivot point 24 on either side of the housing structure by capture pin 58. The free end of injector handle 31 is formed or molded to provide finger or hand grip 29. The handle 30 is of extended length in order to provide sufficient leverage for compressing the drive rod compression spring 42. Extension link 40 can rotate around its handle attachment point 41 permitting the extension link 40 to rotate when the handle 30 is also rotated. A similar pivot connection to the slide frame 45 at pin joint 60 permits extension link 40 to pivot relative to slide frame 45 so that when the handle 30 is rotated down or up the extension link 40 pushes or pulls on the slide frame 45.

In addition to pulling drive rod 43 against compression spring 42, the slide frame 45 has a second function. To ensure good contact of the ampule 25 with the skin of the recipient, during the medicament injection, the injector 20 creates a vacuum at this contact

point of the ampule 25 and the recipient's skin. To achieve this vacuum, the slide frame 45 has attached to it a second connector link 47 extending rearward from latch 48 to engage vacuum piston 35 in the rear of housing 21. The slide frame 45 movement in the rearward direction compresses the compression spring 42 and pulls the drive rod 43 to the cocked position. Simultaneously, connector link 47 which is attached to the upright supports of the slide frame 45 at one end and pin joint 51 by capture pin 58 at the opposite end is attached to piston extension 46 by rod latch pivot pin 54, pulls piston 35 rearward within cylinder 123 which is milled in the rear of housing 21. The piston 35 provides the vacuum for the injector 20, when applied to the recipient's skin, to pull and stretch the skin tight against the suction ports 63, in the ampule 25, which serves to position the outlet orifice 66 correctly for injection of the medicament. In addition, the vacuum system includes a safety device to prevent inadvertent triggering of the injector 20 without first obtaining a good vacuum seal of the ampule 25 to the skin. The safety device comprises a small interlock piston rod 36, which is adapted to engage and disengage a release catch 44 in response to a vacuum generated by piston 35. Interlock piston rod 36 reciprocates within channel 125 and is provided with a small piston 126 on its rearward end which is located within a small cylinder 127 communicating with the cylinder 123 of vacuum piston 35. The piston 35 has an O-ring seal 34 that ensures that the piston can produce a vacuum within cylinder 123 for actuation of the small interlock piston rod 36. The vacuum provided acts on small piston 126 to position the small interlock piston rod 36 to engage or disengage the release arm 55, thereby locking it in a non-release, or unlocking it in a release position. The release arm 55 is able to rotate between the two operating positions around a pivot pin 54 that interfaces with the injector housing structure 21 and is biased to the lock position by torsion spring 33 on pivot pin 54.

A pair of connector links 47 straddle the vacuum piston 35 and are connected to it by piston extension 46. Movement of the slide frame 45 drives the vacuum piston 35, and the vacuum created is ported to the ampule 25 through a suction tube 71. To release the drive rod 43, the injector is provided with a release button 23 which, when pressed, rotates the release arm 55 about pivot pin 54. As the release arm 55 engages release catch 44, rotation of release arm 55 downward causes release catch 44 to pivot upward, releasing drive rod 43

which is then forced forward by drive spring 42 so that the forward end of drive rod 43 enters ampule 25. Release catch 44 rotates around latch pin 58 against torsion spring 53. The release button 23 is installed in the injector housing 21 structure so that when pushed inward it contacts the release arm 55 acting as a cam and causing the release arm 55 to rotate downward and, in turn, lift the release catch 43, that locks the compression spring 42 in its loaded compression position. The release button 23 is retained in the injector housing 21 flush with the housing's outer surface to prevent inadvertent actuation until required by the operating procedure, and is retained in the housing structure with a retention snap ring 32. As noted, release catch 44 includes torsion spring 53 which is tensioned to hold release catch 44 in the lock position to hold the drive rod 43 against the compressed compression spring 42. An angular end surface of release catch 44 provides a means for contact with a corresponding angular end surface of the release arm 55 so that, during the release function, the release catch 44 is pivoted upward around the pivot point provided by the latch pin 58 that engages the housing 21 structure as release arm 55 is pushed downward by button 23.

FIG. 4 shows a cross section view of the injector 20 after injection of the medicament and with the handle 30 rotated away from the housing. To ensure that the drive rod latch 48 always engages, the drive rod retention ring 59, a spring ramp 50 forces the drive rod latch down to engage and lock on to the projecting retention ring 59. The spring ramp is retained by two roll pins 51. To ensure that the drive rod latch 48 releases at the end of the slide frame 45 travel, the latch 48 has a torsion spring 53 that is retained by the pin 58, and drives the latch to the release position around pivot pin 52. To achieve the vacuum, piston 35 has an annular O-ring seal 34 contained within an annular groove in the surface of piston 35 and which engages the wall of cylinder 123. The vacuum generated by piston 35 is conveyed to the ampule 25 by suction passages 73 and vacuum tube 71 which is provided with a seal 70 at the point of interface with the ampule 25 to ensure the function of suction of the skin at ampule contact for efficient injection of the medicament by the injector. When pressed, the injection release button's 23 lower surface cams down the release arm 55 and forces the release catch 44 upward. The release arm 55 rotates around pivot point 57 that holds the pin 54 and torsion spring 33.

To ensure that the release arm cannot accidently be rotated by someone pressing on the button 23 before it is needed and to ensure that the recipient's skin is in contact with the ampule 25 ready for injection, the injector 20 contains a locking feature that prevents the possible release of the drive rod 43. When the handle 30 is rotated, movement of the vacuum piston 35 within cylinder 123 creates pressure or vacuum against small piston 126 resulting in reciprocation of interlock piston rod 36 between the locked and unlocked positions. Pressure generated within cylinder 123 by piston 35 as handle 30 is rotated downward to engage drive rod latch 48 with retention ring 59, pushes interlock piston rod 36 forward into the locked position with release arm 55. Alternatively, rotation of handle 30 upward moves piston 35 rearward within cylinder 123 generating a vacuum which, when ampule 25 is against the skin, is sufficient to act against small piston 126 to draw interlock piston rod 26 rearward, thereby unlocking release arm 55. Until there is full suction on the system, the interlock piston rod 36 is interlocked with the release arm 55 by engagement of the end of rod 36 with mating interlock hole 80 in release arm 55. In this configuration, release arm 55 is incapable of rotation when button 23 is pressed, release catch 44 cannot be pivoted out of engagement with projecting ring 120 which prevents spring 42 from forcing drive rod 43 forward into ampule 25 and no medicament can be ejected. The small piston 126 on interlock piston rod 36 is provided with an O-ring 37 to maintain the vacuum between large piston 35 and the interlock piston rod 36. In the space between the two sealed pistons there is a suction port A 38, shown in FIG. 7, for the transfer of vacuum from cylinder 123 to the ampule 25. To prevent the interlock piston rod 36 from overtraveling, and to hold it in its correct position for activation by the vacuum, the interlock piston rod 36 is retained with a retainer ring 39 in small cylinder 127. To ensure that the large drive compression spring 42 does not drive the drive rod 43 hard against an end stop and does not damage the ampule 25, the drive rod 43 bottoms out on a cushion washer 75 at the end of drive spring chamber 128, when released. FIG. 4 also indicates the surface 69 that contacts the recipient's skin for injection of the medicament. The ampule 25 is expendable and can be easily installed on the injector assembly by rotating the retainer clamp 22 that is detented 26, on to the housing 21 of the injector assembly. *FIG. 5* shows an end view of the injector assembly and end cap 28, with

its attachment screws 76. FIG. 6 provides a cross section view of said housing 21, and indicates the two legs of the slide frame 45 as they straddle the vacuum piston 35.

FIG. 7 provides a sectional view through the housing, and shows the routing and passages through the suction manifold 72. The manifold suction passages 73 supply the necessary vacuum for extracting the interlock piston rod 36 from release arm 55 with a small incoming vacuum for movement of the piston rod 36 into the injector assembly 20. The suction manifold system is comprised of machined vacuum ports 129 in the housing structure to receive the vacuum pressure from the vacuum piston 35 and conduct a vacuum through ported suction passages 73 in the structure within the vacuum piston chamber 123 to the interlock piston chamber 127 and to the suction tubes 71 that interface with the ampule 25 the suction passages are sequentially opened and closed by positioning of the interlock piston 126, and a pair of suction tubes that conduct the suction from the machined-in structure suction passages to the suction ports 63 in the ampule 25.

The injector 20 operating sequence starts by squeezing the handle 30 without an ampule 25 being installed. This causes the drive rod 43 to be pulled back and latched in the cocked position with the compression drive spring 42 compressed between projecting ring 120 and annular abutment surface 124 at the rear end of spring chamber 128. Drive rod latch 48, which catches and draws drive rod 43 back, is spring loaded up and away from drive rod 43 and is only in position to grab the drive rod 43 when in the full forward position due to spring ramp 50. If drive rod 43 has been released, latch 48 will catch the lip of drive rod retention ring 59 and will pull the drive rod 43 back as the handle 30 is squeezed. Latch 48 is provided with a notch 125 in its underside for this purpose. Preferably, drive rod retention ring 59 has a small concave depression in the forward face to engage the notch 125 of drive rod latch 48 and hold it in place while the handle 30 is squeezed. Upon full retraction of drive rod 43 and engagement of projecting ring 120 with release catch 44, drive rod latch 48 disengages from retention ring 59 and is pivoted upward by torsion spring 53 to clear retention ring 59 when drive rod 43 is released.

With the drive rod spring 42 compressed, an ampule 25 is slid into position and ampule retainer clamp 22 is tightened which brings ampule 25 up against seals 70 in the

bottom of the injector nose with the ampule locking tabs 61 engaged with the injector structure. The injector 20 is then placed into position with the ampule 25 on the patient's skin and the handle 30 extended. The handle 30 is squeezed again. Since the drive rod 43 is already back in the cocked position, the drive rod retention ring 59 will not be in position for the drive rod latch 48 to catch on when the handle 30 is extended and squeezed again. As the handle 30 is squeezed the second time, the vacuum piston 35 creates a vacuum in cylinder 123 which is conveyed to suction ports 63 in ampule 25 by suction passages 73 and suction tubes 71. This vacuum stretches the skin tight against the ampule 25 and, when a good seal to the skin is obtained, will cause the interlock piston rod 36 to retract from interlock hole 80 in release arm 55, thereby releasing button 23 for operation. With the handle 30 squeezed, the release button 23 is pressed thereby cumming release arm 55 downward which lifts release catch 44 to disengage from projecting ring 120 thus allowing spring 42 to push drive rod 43 into the ampule 25 providing the force necessary to eject the medicament 31 from the ampule 25 through orifice 66. The button 23 is then released and the handle 30 is returned to the extended position thereby releasing the vacuum and allowing the injector to be pulled away from the skin. Simultaneously, interlock piston rod 36 is forced forward to again engage interlock hole 80 in release arm 55 and lock injector 20 against inadvertent operation. Returning to the start position of the operating sequence, the handle is squeezed, thereby latching and pulling the drive rod 43 back so that the spent ampule can be ejected and replaced with a full one.

A second embodiment of the injector assembly is shown in cross section in FIG. 8 and FIG. 9. For convenience and to avoid confusion, like parts are given the same reference numerals throughout where their function and operation are duplicated or repeated. The major difference between the two embodiments is that the former embodiment utilizes manual operation by the rotation of a hand operated handle 30, while this embodiment utilizes external air supplied power for some of its functions. As discussed above, the primary embodiment utilizes the manual extending downward and retracting of the handle to actuate a large piston 35 to create a vacuum that is utilized for ensuring that the recipient's skin is in direct contact with the injector's injection orifice 66. This manual mechanism also

actuates a means for preventing accidental activation of the injector and a means for compressing the impulse drive spring 42 to a lock position, ready for release by the operator pushing downward on the activation button 23. In this second embodiment of the invention, an external source of pressurized air provides a means whereby the mechanical operations of cocking the drive spring 42 and drive rod 43, generating a vacuum and activating and deactivating the locking safety mechanism are substantially automated so as to occur in response to movement of a trigger assembly 89. The vacuum assist is achieved by the operation of a valve 100 that is controlled by a trigger assembly 89. Movement of the trigger one way, opens the valve for pressure to travel up to a large return piston 83 in extension housing 102 on the rear end of injector housing 21, that pulls back on the vacuum piston 35 to create a vacuum and initiate the same functions achieved by the previous handle movement, connection of the return piston 83 to the vacuum piston 35 being by means of connecting rod 82 passing through the end wall of extension housing 102. Activation of the trigger in the opposite direction closes off the outside pressure source and, in turn, shuts down the vacuum assist function provided by the return piston 83. FIG. 8 and FIG. 9 show this new embodiment in two positions during the injection operation. This embodiment of the needle-free jet injector utilizes external air pressure for activating and sequencing the injector components. The injector 20 is provided with a trigger assembly 89 that is operated by the operator's finger for initiation and movement of an air valve 100 in the injector 20, that opens and blocks externally supplied air pressure from exterior source entering through fitting 49 to a large return piston 83 that is, in turn, connected to the vacuum piston 35 by connecting rod 82. The vacuum piston 35 functions as described in connection with the previous embodiment and provides the vacuum for interlock functions of the release button 23 and the release catch 44 to initiate injection of the medicament. The vacuum piston 35 is moved by the return piston 83 to create a vacuum at the interface contact surface of the recipient's skin and the ampule 25 containing the medicament. The trigger assembly 89 is operated by the injector operator's finger applying a squeezing motion to move the trigger 89 upward, toward the injector activation frame 87 thereby causing the trigger assembly 89 to push against a push rod 90 which actuates a valve 100 to sequence air pressure to enter the

injector from the outside air supply through source fitting 49. The push rod 90 travels fore and aft in a machined support fitting 95 that is attached to the underside of the injector assembly and is retained within the support fitting 95 by a threaded bushing 105 at the end adjacent to the trigger 89 which provides a means for sealing and retention of the air pressure within the support fitting 95. An O-ring seal 92 is captured between the bushing 105 and the support fitting 95, and seals around the push rod 90 where it passes through the bushing 105 and contacts the trigger assembly 89. A like O-ring seal 92 seals around the push rod 90 and seals against the support fitting 95 at the opposite end adjacent to the valve 100. Valve 100 reciprocates in response to fore and aft movement of push rod 90 and is used to sequence the incoming air pressure that enters the valve cavity 130 through two cross pressure ports 91 from the air supply. The valve 100 blocks and opens passage for the incoming pressure to travel into the injector assembly. The valve seals against an O-ring 101 in one direction and seals against the previous O-ring 92 in the opposite direction. The push rod 90 is machined with an undercut 131 to permit air to travel to the valve 100, which then can allow it to pass up into the injector 20, or to be blocked by the valve 100 and its seal. The position of the valve 100 is controlled by the position it is put in by the trigger assembly 89. When the trigger assembly 89 is not activated, the valve 100 is positioned in the air blocked or closed position by a compression spring 99 that is captured by a spring retention plug 98 threaded into the support fitting 95. When the valve 100 is in the blocked or closed position any air pressure captured in the injection on the opposite side of the valve is bled out of the return spring cavity though a pressure bleed hole 97. An O-ring seal 96 is installed at the interface air passage 132 joint between the support fitting 95 and extension housing 102 attached to the injector assembly. The air passage 132 conveys pressurized air from valve 100 into extension housing 102 to drive large return piston 83 that is connected to the vacuum piston 35 by a connecting rod 82. Air pressure behind the return piston 83 pulls on the connecting rod 82 and, in turn, moves the slide frame 45 to accomplish what the handle enacted within the prior injector assembly. The return piston 83 has an O-ring 84 for piston sealing and a compression spring 85 located between return piston 83 and spring retention cap 94 for the return function of the return piston 83. The compression spring 85 is captured in a pocket

133 in the return piston and in a pocket 134 in the spring retention cap 94. Air captured between the retention cap 94 and the return piston 83 is bled out of the cavity through a bleed hole 97. The retention cap 94 is attached to the end of extension housing 102 with retention screws 86. The air pressure into the pressure side of the return piston 83 enters through a port 135 machined in the extension housing 102 and connecting with air passage 132. Plug 93 closes the end of port 135 into vacuum piston cylinder 123. The extension housing 102 is provided with an O-ring seal 81 for sealing pressure around connection rod 82 and preventing air bleed into vacuum piston cylinder 123.

Whereas in the manual embodiment of the injector 20 drive rod 43 is a single piece, the present embodiment includes an alternative structure where the drive rod 43 is divided into two sections, drive rod portion 43' and drive rod portion 43", with an absorbing spring between them. The rearward portion, drive rod 43' includes retention ring 59 with compression drive spring 42 surrounding the shaft between retention ring 59 and a drive cylinder 78 at the forward end of drive rod portion 43'. Separated from drive cylinder 78 is forward drive rod portion 43" which enters ampule 25 when injection occurs. To ensure that drive rod portion 43", when driven by the large drive spring 42, does not unduly impact the ampule plunger 65 and cause a problem on injection of the fluid, a small compressing spring 77 is installed between the rearward end of forward drive rod portion 43" and the drive cylinder 78. This compressing spring 77 ensures that the end of the drive rod portion 43" is in constant contact with the ampule plunger 65 prior to and during injection, thereby avoiding a hard impact between drive rod portion 43" and ampule plunger 65 when the injector is initiated. Compressing spring 77 absorbs the initial shock when release catch 44 is rotated to release position and the tooth release catch 79 disengages with the drive cylinder 78 releasing drive spring 42. The result is that the force of the drive rod portion 43" on ampule piston 65 is constant and the medicament fluid is driven out of the ampule 65 with a smooth high energy force supplied by the large drive spring 42. This alternative, two part drive rod 43 may also be applied to the previous manual embodiment of the injector. FIGS. 10A and 10B provide views showing the connection of the external air supply to the injector and the related manifolding of air passages in the injector.

In a further alternative, the functions of the foregoing pneumatic system may be achieved with an electronic solenoid, or similar electrical or electromagnetic device, powered by batteries or other electrical source. In such an alternative, the solenoid would occupy the space in extension housing 102 in place of the pneumatic piston 83, the plunger of the solenoid being attached to connecting rod 82. A battery pack providing power for the solenoid may be located under the housing 21 in place of support fitting 95, and electrically connected to the solenoid through a switch operated by the trigger assembly 89 or a switch located elsewhere on the housing 21. The operational steps of such an alternative would be the same as the pneumatic embodiment described herein.

Although the preferred embodiment of the injector employs the mechanical compression spring and latch mechanisms to provide the driving force of the impact impulse mechanism, it is certainly within the scope of the present invention to provide the injector in a form that is totally pneumatically or electronically operated. In such modifications, the compression drive spring and mechanical cocking and latching mechanisms would be replaced by equivalent pneumatic and electrical, electronic or electromagnetic actuators to drive both the drive rod 43 and the vacuum piston 35.

In a totally pneumatic alternative, the chamber in which the drive rod latch 48 operates to engage the retention ring 59 on the end of the drive rod 43 would be modified to form a pneumatic cylinder with retention ring 59 modified to form a pneumatically actuated piston with drive rod 43 attached. Appropriate porting would be provided for directing a pneumatic fluid, such as compressed air, to either side of the piston in response to actuation of an appropriate valve, thereby reciprocating the pneumatic piston and the drive rod 43. In addition, means to adjust the pneumatic force may be included thereby providing adjustment of the driving force of drive rod 43 against plunger 65 for intradermal, subcutaneous or intramuscular injections.

In a totally electronically operated injector it would be a simple matter to replace the drive spring 42 with an electronic or electromagnetic actuator, such as a push-pull solenoid, where drive rod 43 forms the reciprocating core. In this alternative, actuation of the solenoid would result in reciprocation of the drive rod 43. With a variable power solenoid and

appropriate voltage regulating means, the driving force generated by the solenoid may be adjusted for subcutaneous, intradermal or intramuscular injections.

Turning now to the ampule 25, this is a key element of the injector device of the present invention as it is the part which holds the medicament to be injected and interfaces with the injector to apply suction generated by the injector to the skin in order to draw the skin tight for proper injection. The ampule 25 further interfaces with the injector to provide proper functioning of the safety interlock in the injector since release of the interlock requires establishing a full suction on the system which cannot be achieved without the ampule 25. With the ampule 25 and injector 20 combination of the present invention it is now possible to achieve needle-less injection of medicament intradermally, subcutaneously or intramuscularly at any angle relative to the surface of the skin.

The basic disposable, pre-filled ampule of the present invention is shown in FIG's. 11, 12 and 13 and provides containment for the medicament and means for attachment to the injector and interface with the vacuum system. The ampule body 67 is preferably made of plastic, glass or equivalent materials or combinations thereof that are suitable for medical use, and is provided with a cylindrical or other shape bore chamber 62 for containing the medicament. Dosage markers 141 are provided on the side of the ampule 25 at the chamber 62 to indicate the amount of medicament in the chamber 62. At the forward end of the bore chamber 62 is the outlet orifice 66, while the rear end of the chamber 62 is closed with an internal ampule plunger seal 65 that captures the medicament inside its chamber. The plunger seal 65 is contacted by the drive rod 43 when the injector is actuated and is pushed forward within the chamber 62 to eject the medicament through the orifice 66.

The shape of the ampule 25 is significant for proper functioning of the injector system, particularly for achieving intradermal injection. In that respect, the body 67 of the ampule 25 is structured such that the nose portion 136 is thinner than the bore chamber portion 137, resulting in a vertical offset 138, or step face, to the lower surface of the ampule 25 as shown in FIG. 11 and 13. This offset 138 effectively creates a pocket 139 in front of the orifice 66 into which the skin surface can be readily drawn by suction from the injector applied through suction ports 63. In addition, the offset 138 of the lower surface permits

ampules to be formed for intradermal, intramuscular and subcutaneous injection that can be used with the same injector 20 simply by changing the thickness of the nose portion 136 of the body 67 while the position of the bore chamber 62 relative to the upper surface of the body 67 remains the same. Thus, an ampule with a thin nose portion 136 will have a greater offset 138 such that the effective level of the chamber 62 will be deeper and more suited to subcutaneous or intramuscular injection, whereas a thicker nosed ampule will have a lesser offset 138 and be suitable for intradermal injection. In this manner, the different ampules can be used with the same injector since the drive rod 43 of the injector and the plunger seal 65 in the bore chamber 62 will always be at the same relative height. This relationship can be seen by comparing FIG. 24, which shows an ampule 25 with a thick nose portion 136 being used for intradermal injection, with FIG. 26, which shows an ampule 25 with a thin nose portion 138 being used for subcutaneous injection.

In a further embodiment, the underside of the ampule immediately surrounding the lower end of the suction ports 63 is preferably formed with a depression or well 140 with the end of the suction port 63 located at the deepest point. This well 140 improves the effect of the suction against the skin and assists in achieving lift of the skin into the pocket 139. It is particularly advantageous for intradermal injections. In ampules having a single suction port 63, the well 140 is preferably circular, whereas in ampules with two or more suction ports 63, individual wells 140 can be formed with each port 63 or a single well 140 accommodating all ports 63 in the ampule can be formed as shown in FIG. 12.

FIG. 12 shows a plan view of the underside of an ampule 25 with two suction ports 63 and a single well 140 encompassing both ports. FIG. 13 shows a longitudinal cross-section view of the ampule 25 with the chamber 62 contoured 68 on its inner surface to provide a precision throat to aid in acceleration of the medicament by reduction of the fluid drag when the ampule 25 receives an impact impulse from the spring loaded drive rod 43 of the injector 20. This reduction of the fluid drag increases the acceleration of the piston 65 resulting in a faster pressure rise and injection of the medicament for the relative force of the compression drive spring 42. Therefore, the medicament 31 is driven out of the ampule 25 with a known controlled impact impulse force.

In addition to the difference in offset 138 resulting from the relative thickness of the nose portion 136 of the ampule body 67, the position and location of the orifice 66 center line relative to the underside plane 69 of the vacuum port 63 can be varied further tailoring the ampules for interdermal, subcutaneous or intramuscular injection medicaments. This also allows injection horizontally or vertically or at any variation of angle therebetween, whether laterally or skewed, through human or animal skin to predetermined depths in the skin layer 64, the dispersement of the medicament in injections being controlled by variation of the angle of the orifice 66 to the vacuum port level plane 69 and the centerline of the ampule. In addition, multiple orifices can be provided to facilitate injection of larger doses or wider injection patterns. As noted previously, the ampule 25 includes locking tabs 61 on each end for engagement with and latching to the injector 20. The locking tabs 61 also serve to correctly position and retain the ampule 25 on the injector 20 for accurate engagement of the suction ports 63 with the vacuum suction tubes 71 and alignment of the drive rod 43 with the chamber 62 and plunger 65. The interface between the surface of the ampule and the suction tubes 71 is sealed by vacuum port seal 70 so as to ensure proper suction through ports 63 to engage recipient's skin for stretching the skin 64 between ports 63 for the medicament injection into recipient's skin 64.

In addition to being prefilled, the ampule 25 may be filled with medicament 31 from an external supply by use of an adaptor assembly 103, shown in FIG. 14, that holds the ampule 25 and seals it for filling the medicament through a rubber seal 104 in the adaptor that aligns with and permits filling of ampule 25 through its orifice 66. The adaptor 103 comprises a housing having means to receive and hold the ampule 25 so that the orifice 66 is in registration with a passage 115 through the rubber seal 104. A standard Luer connector 142 provides a means for attachment of a filling syringe.

An alternative ampule embodiment incorporating means to permit direct filling of the bore chamber 62 with medicament is shown in FIG's 15 through 18. In this embodiment, the ampule is provided with a filling port 143 in the upper surface of the ampule 25 that is closed by a resealable rubber stopper 106.

FIG. 16 shows an unfilled ampule 25 in which filling port 143 connects with bore

chamber 62 through passage 115. A plug 118 closes orifice 66 and protective coverings 107 and 108 maintain the sterility of the ampule surfaces and interior.

FIG. 17 shows the operation of filling the ampule of this embodiment. In this operation, a probe 111 on a nozzle 110 is inserted through the stopper 106 in the filling port 143 of the ampule 25. The nozzle 110 includes a shoulder stop 116 that bears on the upper flat surface 114 of the ampule 25 and locates the probe 11 correctly for the medicament filling. Air must first be evacuated from the ampule passage 115 and the air space 113 within the ampule 25. This is accomplished with the use of syringe 109 and its retraction handle 112 to draw the air out prior to filling the ampule 25 with the medicament. Removal of the probe 111 allows the plug 106 to reseal thereby sealing off the passage 115 and space 113 containing the vacuum. The probe 111 of a nozzle 110 on a syringe 109 containing medicament, or the original syringe 109 now containing medicament, is reinserted through the stopper 106 and the is used to fill the ampule 25 with a prescribed medicament after air evacuation. The pressure of the medicament being injected through probe 11 and passage 115 into space 113, pushes plunger 65 rearward in bore chamber 62.

FIG. 18 shows a means for plugging of the ampule orifice 66 with a plug 118 when filling the medicament. Plug 118 contains an enlarged head 119 for ease of installation and removal with a capture pad 117 to seal against the surface of the ampule 25 and to prevent the plug 118 from being sucked into the orifice 66. A protective outer doubler covering 121 serves as a means to prevent the plug 118 from being driven out of the orifice 66 during filling. All other openings in the ampule 25 are protected with coverings 107 and 108 to maintain full sterile conditions within the ampule 25 and provide for removal and disposal of the ampule orifice plug 118 when protective covering 108 is removed. Preferably, protective coverings 107 and 108 include tabs which may be grasped for easier removal of the shields from the ampule 25.

Referring to the drawings, the preferred embodiment of the invention illustrated in FIG. 1 and FIG. 2 shows the envelope of the needle-free injector top view and side-view respectively. The injector assembly 20 comprises a housing 21 that holds the injector assembly components which are actuated by an external handle 30 and a release button 23,

shown in the top view. FIG. 2 illustrates the means for installation of the medicament filled ampule 25 into the injector 20 and provides access panel 27, end cap 28, and insert fairing 74 as removable units for assembly and service of the injector.

FIG. 3 and FIG. 4 provide a cross section view of the injector assembly with the handle 30 in both a rotated up and a rotated down position and the resultant position of all of the components contained in the housing 21 respectively. This embodiment covers the use of a single prefilled ampule 25 and shows how it is captured in the injector assembly. The ampule 25 has projecting tabs 61 that engage a notched cavity in the insert fairing 74 at one end are and positioned and retained against the nose of the housing 21 at the other end with retainer clamp 22 that pivots outward away from the ampule 25 to release it and provide for replacement after the ampule 25 has been used. The ampule 25 includes at least one vacuum suction port 63 for interfacing with the injection recipient's skin. The ampule 25 installation in the injector 20 positions the ampule 25 under and against a seal 70 that provides sealing between the ampule 25 and a pair of suction tubes 71 that are utilized to convey a vacuum to the ampule vacuum ports 63. The suction tubes 71 at their opposite ends interface with a machined-in manifold 72 in the housing 21. The ampule retainer clamp 22 is retained in the ampule capture position with a detent projection on the retainer clamp that engages a small pocket in the housing 21 and, when the retainer clamp 22 is in the ampule retention position, the clamp 22 snaps into the pocket for firm retention. On release of the clamp 22 it is rotated around the upper detent pocket for ampule removal.

To eject medication fluid 31 out of the ampule 25, a drive rod 43 travels in a bored hole in the housing 21 structure and is driven into a chamber opening in said ampule 25 contacting a plunger 65 therein to force under pressure the fluid out of the ampule 25 through an orifice 66. The drive rod 43 is driven into the ampule 25 by a large compression drive spring 42 that applies load against a projecting ring 120 on the drive rod 43 and at the opposite end against an abutment surface 124 of the housing structure. To compress the drive spring 42, the injector assembly is provided with handle 30 that straddles the assembly and pivots around a pinned pivot 24. When the handle 30 is rotated up toward the housing 21, the compression spring 42 is compressed and is retained at the preloaded compressed location by

a release catch 44 that pivots around a pin 58 containing a torsion spring 53. The torsion spring 53 preloads the release catch 44 down to readily latch the drive rod 43 when the projecting drive rod ring 120 passes by the tooth 79 of release catch 44.

To compress the compression spring 42 that encircles the drive rod 43, the drive rod 43 also has, at its rearward end termination, retention ring 59 that is used by drive rod latch 48 to pull on the drive rod 43 and compress the compression spring 42 in response to upward rotation of the handle 30. To achieve this compression and loading up of the compression spring 42 when the handle 30 is rotated upward, the handle 30 connects to a link 40 that has pivot points 41 and 60 at each end and connects to slide frame 45 that slides in machined grooves in the housing 21. The slide frame 45 is moved horizontally in the grooves by the handle 30 pushing the link 40 that in turn moves the slide frame 45. FIG. 3 and FIG. 4 illustrate the two positions of the slide frame 45 and the handle 30. An upright leg on the slide 45 is attached to the drive rod latch 48 that is used to pull the drive rod 43 and compression spring 42 to the compressed loaded energy stored condition. The drive rod latch 48 pivots around a pivot point pin 52 that holds and engages a connecting link 47 and a torsion spring 53 that biases the drive rod latch 48 upward to the unlatched position to ensure that drive rod 43 will be released when the injector 20 is actuated.

To ensure that the drive rod latch 48 will rotate downward against the torsion spring load the drive rod latch 48 is guided down to the latched lock position with a ramp 50. The ramp 50 is retained in the housing structure 21 with two roll pins 51 and the ramp 50 is sloped to match the angular end termination of the drive rod latch 48. The drive rod latch 48 includes a projecting hook surface on the opposite side of the latch to catch and hold the drive rod retention ring 59 for pull back. The drive rod retention ring 59 preferably has a concave depression in the forward face to ensure that the projecting hook of the drive rod latch 48 will stay engaged while the handle 30 is squeezed to pull the drive rod 43 back. When the release catch 44 is released, the compression spring 42 drives the drive rod 43 into the ampule 25 and injects the fluid out of the orifice 66 in the ampule 25. To minimize impact noise of the drive rod projecting ring 120 and compression spring 42 striking an end stop, the forward side of the drive rod projecting ring is provided with a plastic or rubber washer 75 for noise

deadening purposes.

The connector link 47 that is connected to the slide frame 45 is connected at its opposite end to a pin 54 that engages an extension 46 on a piston 35 that provides a vacuum for the ampule vacuum ports 63. When the slide frame 45 is moved horizontally in the machined grooves in the housing structure, the connecting link 47 moves the piston in and out in its cylinder 123. To achieve a vacuum behind the piston 35, the piston 35 includes an O-ring seal 34. The vacuum created is transmitted through suction passages 73 in the structural manifold 72 to the suction tubes 71 and, in turn, to the vacuum ports 63 in the ampule 25 as shown in FIG. 7. The vacuum created by the movement of the piston 35 retracts an interlock piston rod 36 that provides a means for locking and unlocking a release arm 55. Two vacuum port openings in the manifold 72 cycle the interlock piston rod 36 back and forth when interlock is required. The interlock piston 126 is provided with an O-ring seal 37 and a retainer ring 39 controls the length of its movement stroke and captures it in its cylinder 127.

The interlock piston rod 36 extends into the release arm 55 for locking and retracts out of the release arm 55 for unlocking. The release arm 55 pivots about a pivot pin 54 that includes a torsion spring 33 that positions the arm 55 for engagement with the piston rod 36. When the release arm 55 is in the horizontal position, as the result of torsion spring 53 load, the release arm 55 rests against the bottom surface of a release button 23 that is held in the housing 21 with a snap ring 32. When the release button 23 is pressed down by the operator it presses down on the release arm 55 and rotates it, which in turn drives the release catch 44 upward to disengage from the drive rod 43, which is then driven into the ampule 25 by the compression spring 42 and injects the medicament into the skin tissue of the recipient.

The ampule 25 is illustrated in FIG. 11 side view and FIG. 12 shows a top view of the ampule 25. The ampule 25 is manufactured from one or more of a variety of plastics, or glass, or equivalent medical grade materials. The ampule 25 has at least one vacuum port 63 for use in positioning, stretching and holding the recipient's skin 64. The ampule 25 further has at least two locking tabs 61 and an internal cylinder bore chamber 62 for containment of the preloaded medicament. Dosage markers are provided on the outer surface of the ampule

25 adjacent to the bore chamber 62. Contained within the bore chamber 62 is an ampule plunger 65, shown in FIG. 11 that captures and contains the medicament within the bore chamber 62 and transfers the force of the drive rod 43 to the medicament to eject the medicament from the ampule 25 through the orifice 66. The bore chamber 62 is preferably contour shaped 68 to enhance the injection process. The ampule 25 and the injector 20 are unique in that the ampule 25 uses a vacuum produced by the injector 20 to stretch and properly hold the recipient's skin for the medicament to be injected into the skin. Stretching the skin increases permeability which reduces the amount of energy required to inject fluid into a tissue. Injecting the fluid horizontally to the skin allows controlled positioning of the tissue for ID, Sub-Q and IM injections. The bore 62 and orifice 66 are designed to accelerate the fluid with minimal drag by a refined throat contour 68. The size and length of the ampule's bore are also optimized to minimize turbulent flow and thus drag and this will reduce pain and energy required to penetrate the epidermal tissue. This process of injection of medicament fluid into the tissue spreads the particles of the medicament over a larger area than using a needle syringe and, in turn, decreases the local pressure in the tissue and eliminates leakage of the fluid from the injection opening in the tissue, which in turn reduces possibility of spreading infections.

A further embodiment of the invention is illustrated in FIG. 19 which shows the side view of the injector 20 of the present invention adapted to receive and fitted with a multiple ampule assembly 200. The function, operation and internal components of the injector 20 are the same as those presented previously in the said single ampule embodiments with the exception of the ampule, its attachment to and retention on the injector 20 and the technique of ampule replacement. FIG. 12 illustrates a cross section view of the multiple ampule injector assembly with manual embodiment single ampule injector components. The air powered embodiment may be similarly modified to receive the multiple ampule assembly 200. Since the mechanical operation of the manual and air powered injectors 20 is the same as described previously herein, the description thereof will not be repeated except as necessary to for a clear understanding of the multiple ampule embodiment.

The multiple ampule injector housing 201 comprises a rotatable multiple unit

cartridge 205 that contains multiple medicament filled ampules 25 molded into a plastic or equivalent material cylinder 222 as shown in FIG. 21 and FIG. 22. The cylinder 222 is rotatable around a center shaft 206 as shown in FIG. 20 and FIG. 21. The cylinder 222 is manually rotated by a rotation knob 208 rotatably attached to the end of the shaft 206. The cartridge 205 containing the ampules 25 is keyed to the shaft 206 by a sleeve 209 to provide a means for rotation and positioning of the ampules 25 for fluid injection. A position detent 207 is installed in the injector housing 21 and positions and detents into a series of pockets 204 in the rim of the cartridge 205. In addition, a similar detent 214 in the injector housing 21 engages an annular groove 213 adjacent to the end of the shaft 206 to capture and hold the multiple unit assembly 200 on to the end of the injector 20. Preferably the detents 207 and 214 are ball 215 and spring 216 mechanisms as shown, but other detent mechanisms providing similar function may be used.

The rotation knob 208 is keyed and retained on the sleeve 209 with a knob capture pin 223 so that when the knob is rotated it rotates the cartridge 205 in the housing 201 around the shaft 206 but does not rotate the shaft 206 itself. The sleeve 209 attached to the knob 208 keys in the cartridge 205 and turns it to the various ampule positions whereupon the position detent 207 engages the pocket 204 for that position and holds the ampule 25 in registration with the drive rod 43.

In the cartridge 205 of the multiple unit 200 each ampule 25 contains a set of vacuum ports 203, preferably two, but at least one, and an internal cylinder bore chamber 62 for containment of the preloaded medicament. As with the single ampule embodiment, each ampule 25 of the multiple unit 200 is provided with dosage markers on its outer surface. Also, each ampule 25 contains within its bore chamber 62 an ampule plunger 212 that captures and contains the said medicament. Similarly, the bore chambers 62 duplicate the contour shape, size, length and configuration as presented in the prior single ampule embodiment and, therefore, the injection procedure, method of injection and results of the injection are identical.

The multiple unit assembly 200 contains a similar suction tube 210 and a seal 211 for interface with each ampule that is positioned for fluid injection. A stepped surface on the

cartridge's sleeve 209 bears down on the suction tube 210 to enhance the seal 211 interface between the suction tube 210 and the ampule 25. The suction tube 210 connects to the injector's manifold system in a manner identical to the previous embodiments.

On the outside surface of the multiple unit housing 201 there is a window 221 that reveals by means of an electronic code 219 and sequential number 222, the status of the various ampules 25 in the cartridge 205. This data reveals the medicament and the dose used, date of filling, name of the supplier laboratory and/or other pertinent information. As with the single ampules, each individual ampule of the multiple unit may be protected by a removable tab 220 prior to use.

In use, a multiple unit ampule assembly 200 having the desired medicament preloaded in the ampules 25 will be selected and installed on the injector 21 by insertion of the end of shaft 206 into a blind shaft receiving hole 218 bored in the end of injector housing 21 until detent 214 engages the groove 213 in the end of shaft 206, thereby holding multiple unit assembly 200 in place. The engagement of detent 214 and groove 213 is of sufficient strength to hold multiple unit assembly 200 in place against inadvertent displacement, but not so strong that the multiple unit assembly 200 cannot be readily removed for replacement another assembly 200. With the multiple unit assembly 200 in place, knob 208 is rotated to bring an ampule into position and the injector is operated as previously described. To ready the injector for the next injection using the same multiple unit assembly 200, one simply re-cocks the injector as has been described thereby withdrawing the drive rod from the now used ampule 25 and rotates the knob 208 to bring the next ampule into position. When all ampules in the multiple unit have been depleted, or if a different multiple unit is desired, one grasps the housing 201 of the multiple unit 200 and pulls it from the injector.

While there have been described above the principles of this invention in connection with specific methods and apparatus, it is to be clearly understood that this description is simply illustrative and numerous other arrangements may be devised by those skilled in the art, which will embody the spirit of the invention and which fall within the scope of the following claims.

We claim:

1. A needle free hypodermic injector comprising:

a hand manipulatable elongated housing,

an impact impulse injection mechanism within said housing,

a suction generating means within said housing and cooperable with said impact impulse injection mechanism,

a safety interlock mechanism,

at least one medicament containing ampule cooperable with said impact impulse injection mechanism and said suction generating means and having at least one jet orifice through which medicament is injectable through a skin surface in response to an impulse placed on said medicament by said impact impulse injection mechanism, and

means to receive and hold said ampule on said injector in registration with said impact impulse injection mechanism and in communication with said suction generating means,

whereby said injector is adapted to expel said medicament from said ampule in a jet stream of sufficient velocity to penetrate skin tissue held against said orifice by said suction generating means and to deposit said medicament intradermally, subcutaneously or intramuscularly based on the position and angle of said jet orifice and the force provided by said impact impulse injection mechanism.

2. The needle free hypodermic injector of claim 1 wherein said ampule comprises an elongated body having a forward end, a rearward end, a substantially planar upper surface and a lower surface having a downward offset between said forward end and said rearward end, said offset providing a forward facing step face, a horizontally disposed bore within said body extending from the rearward end of said body to a point substantially adjacent to said step face, said bore being open at said rearward end and having a sealing plunger disposed therein, said bore further having at least one jet orifice extending through said step face, whereby said bore is capable of holding a quantity of medicament injectable through a skin surface held against said orifice in response to said plunger being driven forward in said bore by said impact impulse injection mechanism.

3. The needle free hypodermic injector of claim 2 wherein said ampule further comprises at least one suction port extending vertically through said body from said upper surface to said lower surface at a point forward of said step face, said suction port being in fluid communication with said suction generating means whereby a suction generated by said suction generating means is applicable to said skin surface through said port whereby said skin surface is drawn against said lower surface of said ampule and said jet orifice prior to injection of said medicament.

4. The needle free hypodermic injector of claim 3 wherein said impact impulse injection mechanism comprises:

a drive rod linearly reciprocatable within said housing between a cocked position and an injection position and having a forward portion adapted to project from said housing into said ampule bore to contact and drive said plunger upon movement of said drive rod from said cocked position to said injection position,

a compressible drive spring concentrically disposed along a rear portion of said drive rod between a stationary abutment and a projection substantially midway along said drive rod,

a releasable latch mechanism adapted to engage said projection and hold said drive rod in said cocked position with said spring compressed, and

a cocking mechanism adapted to draw said drive rod rearward to said cocked position,

whereby actuating said cocking mechanism draws said drive rod rearward in said housing compressing said drive spring between said stationary abutment and said projection and positioning said drive rod such that said latch mechanism engages said projection thereby holding said drive rod in said cocked position ready for injection and releasing said latch mechanism allows said spring to decompress thereby driving said drive rod forward to engage said plunger in said ampule and drive said plunger against said medicament whereby said medicament is forced through said orifice and injected into said skin surface.

5. The needle free hypodermic injector of claim 4 wherein said suction

generating means comprises a reciprocating piston disposed in a cylinder in said housing, said piston being mechanically connected to said cocking mechanism whereby said piston is moved in said cylinder concurrently with cocking of said drive rod thereby creating a suction behind said piston, and means providing fluid communication between said cylinder and said ampule whereby said suction is conveyed from said cylinder to said ampule suction port.

6. The needle free hypodermic injector of claim 5 wherein said safety interlock mechanism comprises a reciprocating rod responsive to said suction and adapted to engage said latch mechanism in response to incomplete suction applied through said ampule suction port to said skin surface, whereby said latch mechanism is prevented from operating to release said drive rod and drive spring from said cocked position in the absence of secure contact of said ampule with said skin surface.

7. The needle free hypodermic injector of claim 3 further comprising a concave depression in said lower surface of said ampule surrounding and concentric with said suction port, whereby a suction generated by said suction generating means is applicable to said skin surface through said port whereby said skin surface is drawn against said lower surface of said ampule into said depression and against said jet orifice prior to injection of said medicament.

8. The needle free hypodermic injector of claim 7 wherein said jet orifice is located in said step face adjacent to an upper edge thereof and horizontally along a centerline of said bore whereby said ampule is adapted for intradermal injection of medicament.

9. The needle free hypodermic injector of claim 7 wherein said jet orifice is located in said step face at a downward angle relative to a centerline of said bore whereby said ampule is adapted for subcutaneous or intramuscular injection of medicament.

10. The needle free hypodermic injector of claim 2 wherein said ampule further comprises two suction ports laterally spaced on opposite sides of a center line of said ampule and extending vertically through said body from said upper surface to said lower surface at a point forward of said step face, said suction ports being in fluid communication with said suction generating means, said ampule further comprising a concave depression in said lower surface encompassing the lower ends of said suction ports, whereby a suction generated by

said suction generating means is applicable to said skin surface through said ports whereby said skin surface is drawn against said lower surface of said ampule into said depression and against said jet orifice prior to injection of said medicament.

11. A needle free hypodermic injector comprising an injector assembly and at least one medicament containing ampule removably attachable to said injector assembly, said injector assembly comprising an elongated hand manipulatable housing, said housing comprising:

a main body portion containing a mechanical impact impulse means comprising a drive rod linearly reciprocatable within said housing between a cocked position and an injection position, a compressible drive spring linearly concentric about a rear portion of said drive rod, said spring being confined between a stationary abutment within said housing and a projection substantially midway along said drive rod whereby rearward displacement of said drive rod compresses said spring, a latch mechanism cooperating with said projection to releasably hold said drive rod in a cocked position wherein said spring is compressed, a release means to release said latch mechanism when injection is desired, and a cocking means cooperating with said drive rod and operable to draw said drive rod in a rearward direction to said cocked position thereby compressing said spring and engaging said latch mechanism;

a forward nose portion adapted to removably receive said at least one ampule and having detent means to releasably secure said ampule to said injector assembly when said impact impulse mechanism is in said cocked position, said at least one ampule comprising a body having a forward end and a rearward end, a substantially planar upper surface and a stepped lower surface having a forward facing step face therein, said body having formed therein behind said step face a horizontally disposed substantially cylindrical medicament chamber open at said rearward end and narrowing to at least one jet orifice in said step face, said chamber being sized and positioned to receive a forward end of said drive rod when said ampule is secured to said injector assembly and said latch mechanism is released, said chamber further containing a sealing plunger providing a means to retain medicament in said chamber, said plunger adapted to be engaged by said drive rod upon release of said latch

mechanism, whereby said drive rod drives said plunger forward within said chamber forcing said medicament under pressure through said jet orifice for injection into a skin surface held against said ampule.

12. The needle free hypodermic injector of claim 11 further comprising at least one suction port vertically disposed through said ampule body forward of said jet orifice, a suction generating means disposed in said main body portion of said housing and suction conduits within said housing and said nose portion providing fluid communication between said suction generating means and said at least one suction port whereby suction generated by said suction generating means is conveyed to said at least one suction port of said ampule, said suction serving to draw said skin surface against said ampule and said orifice prior to injection.

13. The needle free hypodermic injector of claim 12 wherein said suction generating means comprises a piston reciprocatable within a cylinder in said housing, said piston being connected to and operable by said cocking means to generate said suction.

14. The needle free hypodermic injector of claim 13 further comprising a suction operated interlock adapted to lock said latch mechanism against inadvertent operation in response to insufficient suction applied to said skin surface, said interlock comprising a piston operating within a cylinder adjacent to said suction generating means and fluidly connected thereto by said suction conduits, said piston having a locking rod projecting longitudinally therefrom, said locking rod having an end remote from said piston adapted to engage said latch mechanism when said interlock is in said locked position and to disengage from said latch mechanism when sufficient suction is applied to the skin through said ampule thereby permitting release of said drive rod and spring from said cocked position whereby said drive rod moves forward to engage and drive said plunger within said ampule chamber.

15. The needle free hypodermic injector of claim 14 wherein said cocking means comprises a handle pivoted to said housing, a slide frame within said housing mechanically connected to said handle so as to reciprocate within said housing upon pivoting of said handle, a drive rod latch attached to said slide frame and adapted to engage said drive rod when said handle is pivoted away from said housing and to draw said drive rod rearward

against the force of said compression drive spring when said handle is pivoted toward said housing, said drive rod latch being biased to disengage from said drive rod upon engagement of said latch mechanism, and a mechanical link between said slide frame and said piston of said suction generating means whereby said piston is moved within said cylinder when said handle is pivoted and generates a suction at said ampule when said handle is pivoted toward said housing.

16. The needle free hypodermic injector of claim 14 wherein said cocking means comprises a pneumatically operated piston within said housing, a source of compressed air, air conduits, a trigger operated valve, a slide frame within said housing mechanically connected to said pneumatically operated piston so as to reciprocate within said housing upon actuation of said piston, a drive rod latch attached to said slide frame and adapted to engage said drive rod when said pneumatically operated piston is driven in a first direction and to draw said drive rod rearward against the force of said compression drive spring when said pneumatically operated piston is driven in a second direction, said drive rod latch being biased to disengage from said drive rod upon engagement of said latch mechanism, and a mechanical link between said slide frame and said piston of said suction generating means whereby said suction piston is moved within said suction piston cylinder when said pneumatically operated piston is actuated and generates a suction at said ampule when said pneumatically operated piston is driven in said second direction.

17. The needle free hypodermic injector of claim 13 further comprising a concave depression in said lower surface of said ampule surrounding and concentric with said suction port, whereby a suction generated by said suction generating means is applicable to said skin surface through said port whereby said skin surface is drawn against said lower surface of said ampule into said depression and against said jet orifice prior to injection of said medicament.

18. The needle free hypodermic injector of claim 17 wherein said jet orifice is located in said step face adjacent to an upper edge thereof and horizontally along a centerline of said bore whereby said ampule is adapted for intradermal injection of medicament.

19. The needle free hypodermic injector of claim 17 wherein said jet orifice is

located in said step face at a downward angle relative to a centerline of said bore whereby said ampule is adapted for subcutaneous or intramuscular injection of medicament.

20. The needle free hypodermic injector of claim 11 wherein said ampule further comprises two suction ports laterally spaced on opposite sides of a center line of said ampule and extending vertically through said body from said upper surface to said lower surface at a point forward of said step face, said suction ports being in fluid communication with said suction generating means, said ampule further comprising a concave depression in said lower surface encompassing the lower ends of said suction ports, whereby a suction generated by said suction generating means is applicable to said skin surface through said ports whereby said skin surface is drawn against said lower surface of said ampule into said depression and against said jet orifice prior to injection of said medicament.

21. The needle free hypodermic injector of claim 14 wherein said at least one ampule comprises a multiple ampule assembly comprising a plurality of identical ampules arranged about and parallel to a center shaft in a cylindrical assembly, said cylindrical assembly being rotatable about said shaft for sequential registration of each ampule in said assembly with said drive rod and said suction conduits, said forward nose portion of said housing having a socket into which said center shaft is received, said socket and said shaft having cooperating detent means to removably secure said multiple ampule assembly to said injector housing, and said nose portion having detent means cooperable with said ampules to ensure accurate registration of each of said ampules in turn with said drive rod and said suction conduits.

22. The needle free hypodermic injector of claim 14 wherein said at least one ampule further comprises a filling port disposed in said upper surface of said body, said filling port comprising a conduit providing fluid communication with the forward end of said chamber and a self sealing plug within said conduit adapted to receive a needle or probe of a filling syringe for injecting medicament into said chamber, said ampule further comprising a removable plug temporarily closing said jet orifice during filling and removable protective seals over said filing port, said removable plug and said open rearward end of said chamber.

23. The needle free hypodermic injector of claim 14 wherein said cocking means

comprises an electrically actuated solenoid within said housing, a source of electrical power, electrical circuits, a trigger operated switch, a slide frame within said housing mechanically connected to said solenoid so as to reciprocate within said housing upon actuation of said solenoid, a drive rod latch attached to said slide frame and adapted to engage said drive rod when said solenoid is actuated in a first direction and to draw said drive rod rearward against the force of said compression drive spring when said solenoid is actuated in a second direction, said drive rod latch being biased to disengage from said drive rod upon engagement of said latch mechanism, and a mechanical link between said slide frame and said piston of said suction generating means whereby said suction piston is moved within said suction piston cylinder when said solenoid is actuated and generates a suction at said ampule when said pneumatically operated piston is driven in said second direction.

24. The needle free hypodermic injector of claim 14 wherein said drive rod is divided into two sections, a rear section with said compression drive spring concentric thereabout and a forward section adapted to enter said ampule, and a shock absorbing means uniting said front and rear sections, whereby said shock absorbing means operates to absorb the initial impact shock of release of said drive spring whereby the impulse of said drive rod against said ampule plunger is smooth and constant.

25. The needle free hypodermic injector of claim 4 wherein said drive rod is divided into two sections, a rear section with said compression drive spring concentric thereabout and a forward section adapted to enter said ampule, and a shock absorbing means uniting said front and rear sections, whereby said shock absorbing means operates to absorb the initial impact shock of release of said drive spring whereby the impulse of said drive rod against said ampule plunger is smooth and constant.

26. The needle free hypodermic injector of claim 3 wherein said impact impulse injection mechanism comprises:

a drive rod linearly reciprocatable within said housing between a cocked position and an injection position and having a forward portion adapted to project from said housing into said ampule bore to contact and drive said plunger upon movement of said drive rod from said cocked position to said injection position,

a pneumatic means reciprocating said drive rod between said cocked position and said injection position, and

a manually operated valve means actuating said pneumatic means,

whereby a first actuation of said pneumatic means draws said drive rod rearward in said housing allowing attachment of an ampule to said injector and a second actuation of said pneumatic means drives said drive rod forward to engage said plunger in said ampule and drive said plunger against said medicament whereby said medicament is forced through said orifice and injected into said skin surface.

27. The needle free hypodermic injector of claim 3 wherein said impact impulse injection mechanism comprises:

a drive rod linearly reciprocatable within said housing between a cocked position and an injection position and having a forward portion adapted to project from said housing into said ampule bore to contact and drive said plunger upon movement of said drive rod from said cocked position to said injection position,

a solenoid means reciprocating said drive rod between said cocked position and said injection position, and

a manually operated switch means actuating said solenoid means,

whereby a first actuation of said solenoid means draws said drive rod rearward in said housing allowing attachment of an ampule to said injector and a second actuation of said solenoid means drives said drive rod forward to engage said plunger in said ampule and drive said plunger against said medicament whereby said medicament is forced through said orifice and injected into said skin surface.

28. The needle free hypodermic injector of claim 6 wherein said cocking mechanism comprises a pneumatically actuated piston, a slide frame within said housing mechanically connected to said pneumatically actuated piston so as to reciprocate within said housing upon pneumatic actuation of said pneumatically actuated piston, valve means directing pneumatic fluid to said pneumatically actuated piston, a drive rod latch attached to said slide frame and adapted to engage said drive rod upon actuation of said piston, said drive rod latch being biased to disengage from said drive rod upon engagement of said releasable

latch mechanism, and a mechanical link between said pneumatically actuated piston and said suction generating means whereby said suction generating means is actuated when said pneumatically actuated piston is actuated.

29. The needle free hypodermic injector of claim 6 wherein said cocking mechanism comprises an electrically actuated push-pull solenoid having a reciprocating core, a slide frame within said housing mechanically connected to said reciprocating core so as to reciprocate within said housing upon actuation of said solenoid, an electrical power source, switch means connecting said electrical power source and said solenoid operable to actuate said solenoid, a drive rod latch attached to said slide frame and adapted to engage said drive rod upon actuation of said solenoid, said drive rod latch being biased to disengage from said drive rod upon engagement of said releasable latch mechanism, and a mechanical link between said solenoid and said suction generating means whereby said suction generating means is actuated when said solenoid is actuated.

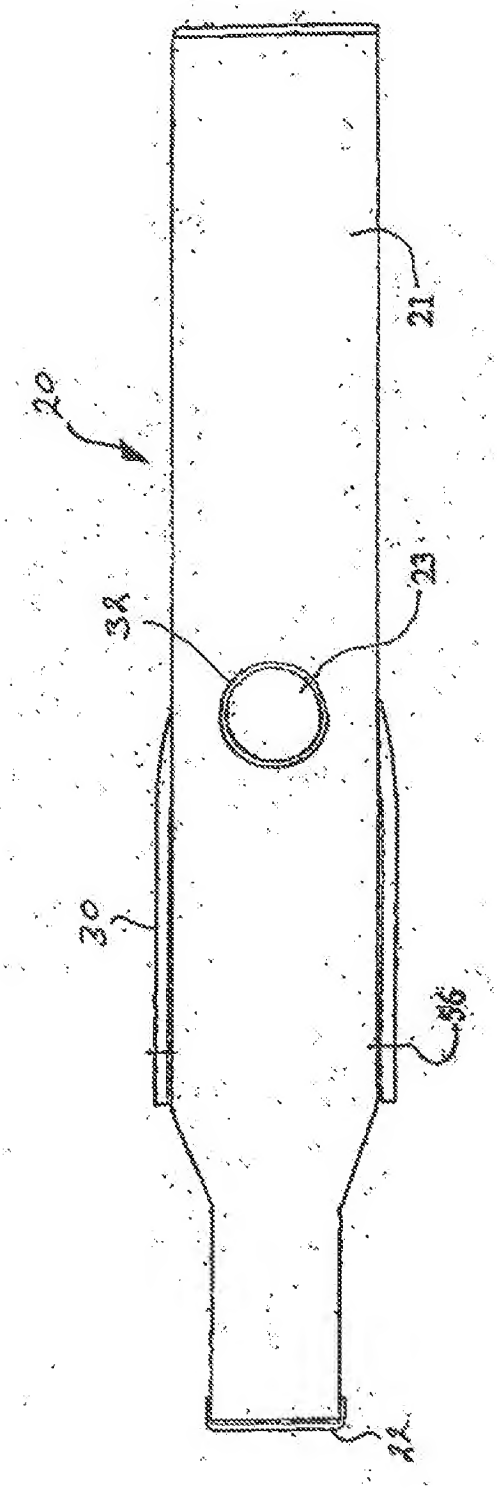

FIG.1

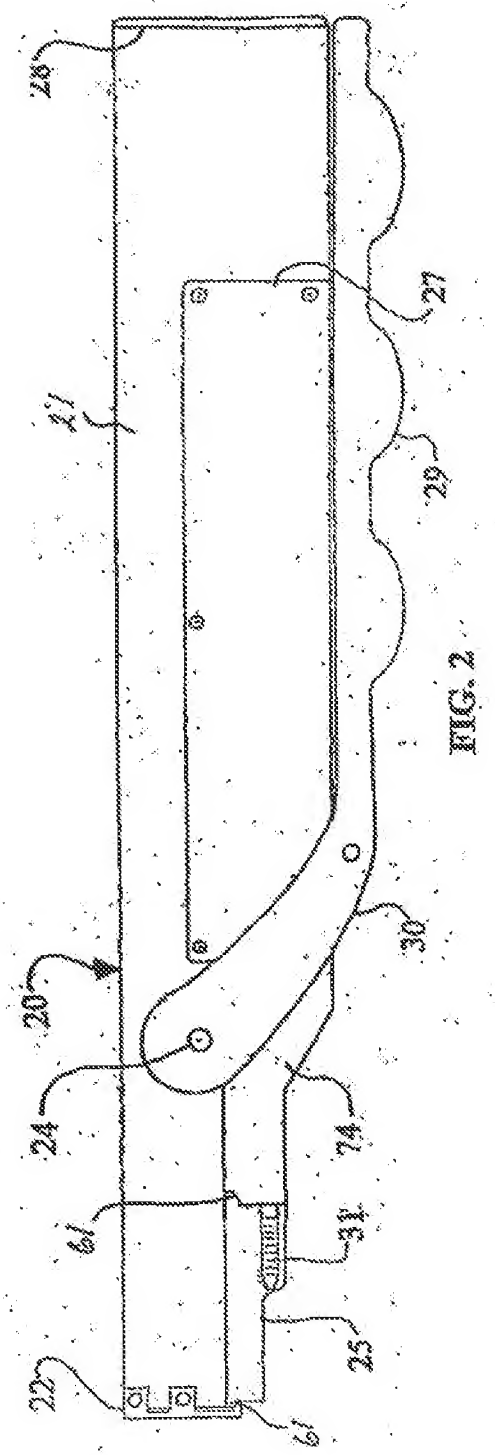

FIG. 2

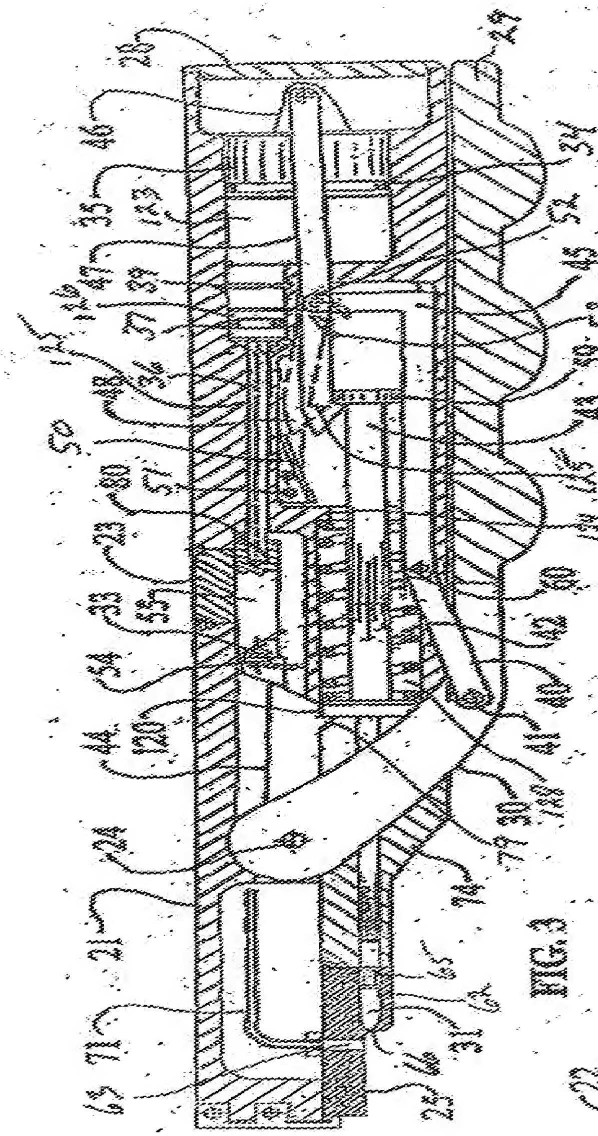

FIG. 3

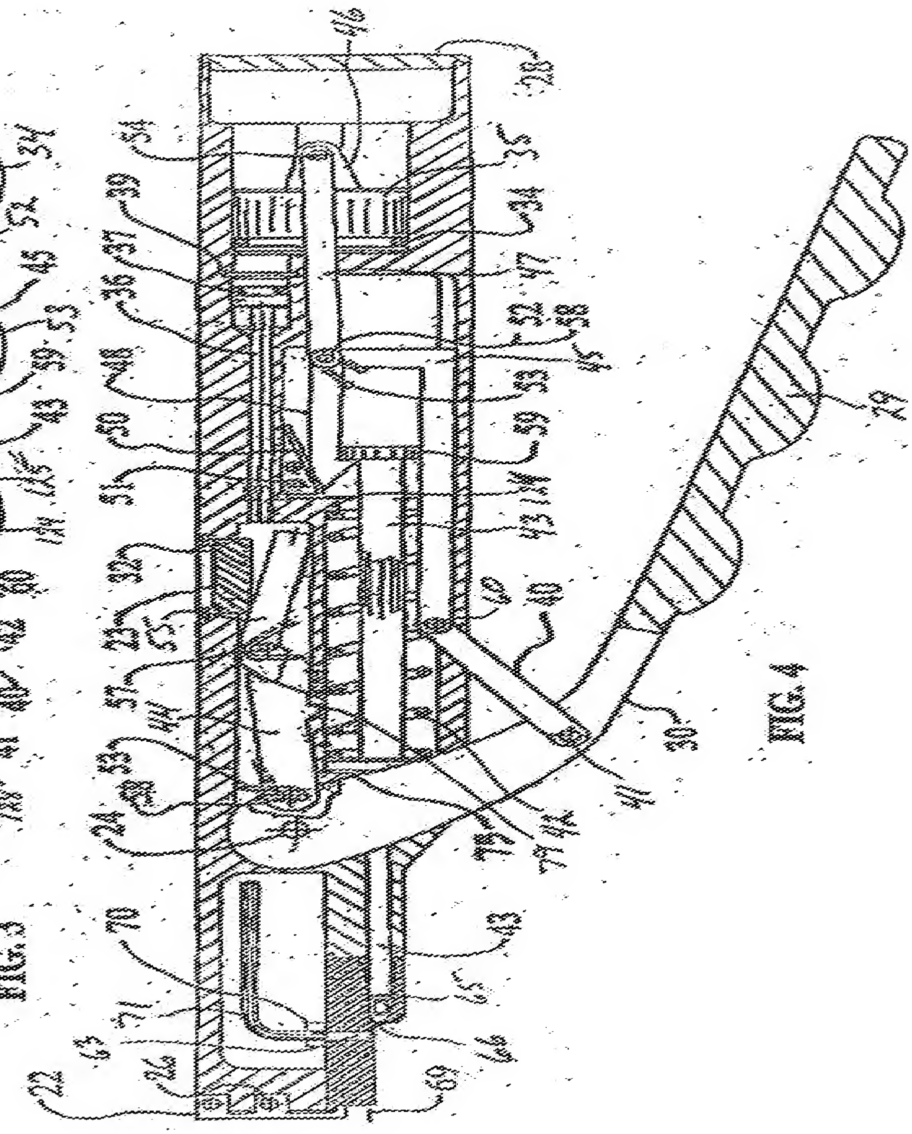

FIG. 4

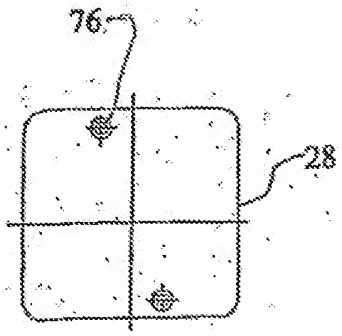

FIG. 5

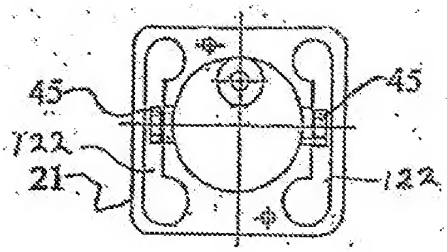

FIG. 6

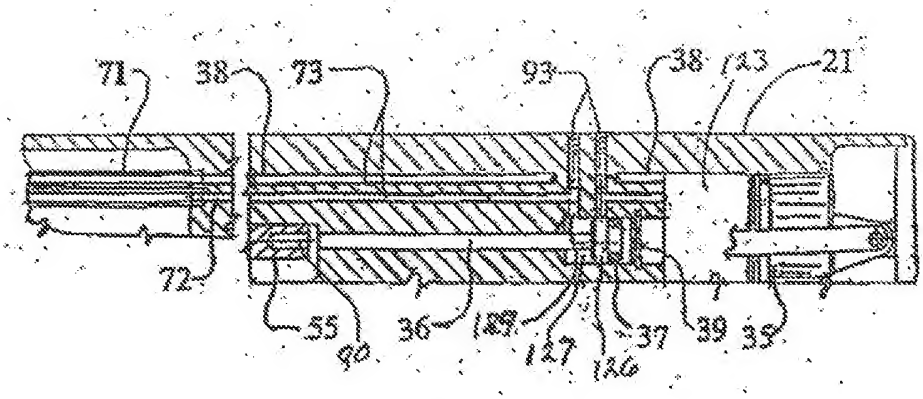

FIG. 7

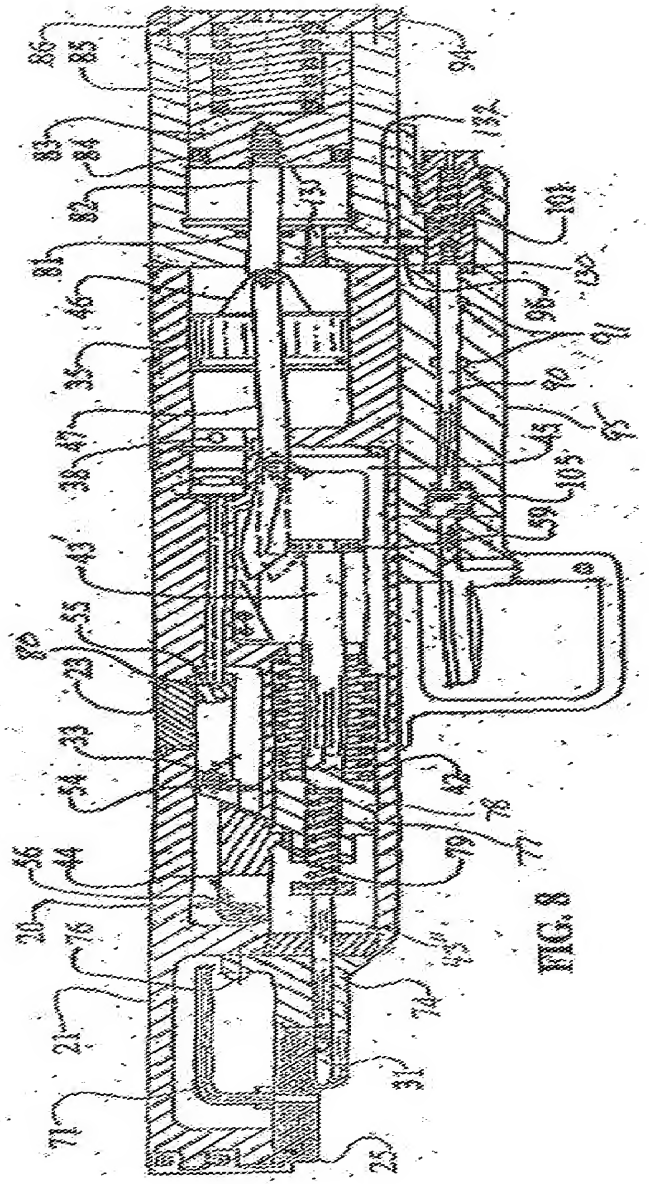

FIG. 8

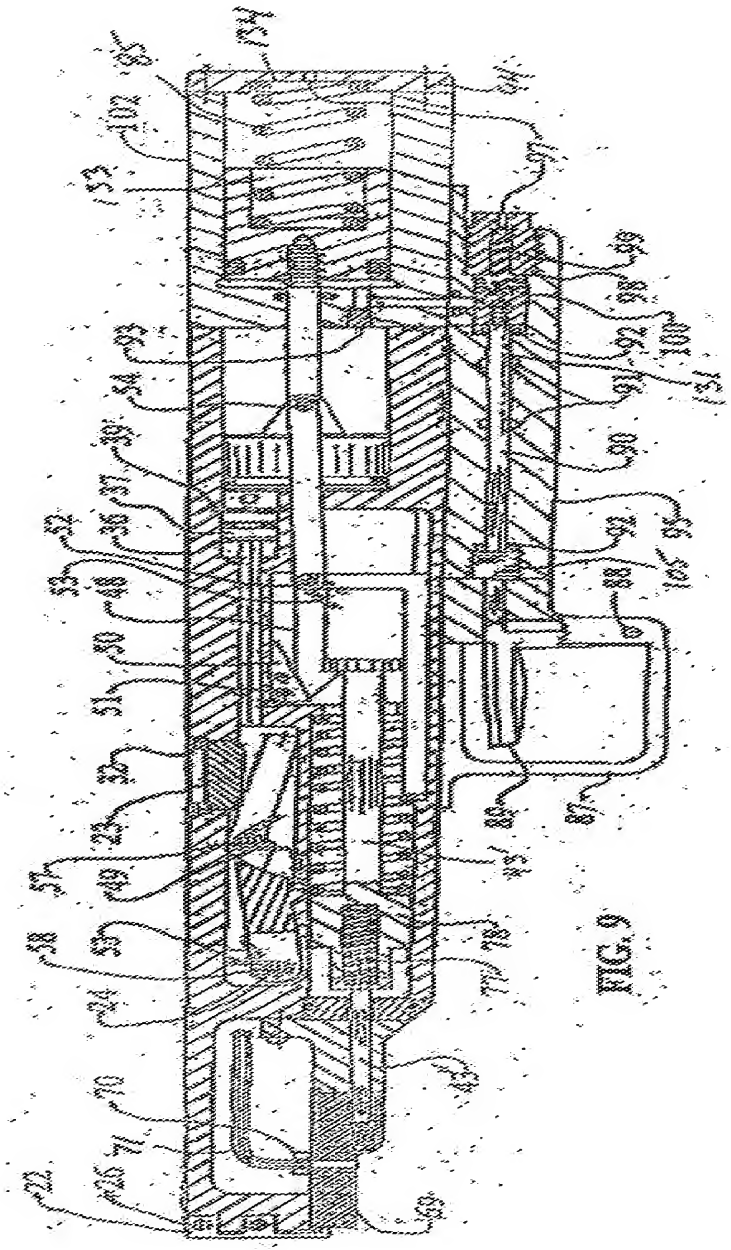

FIG. 9

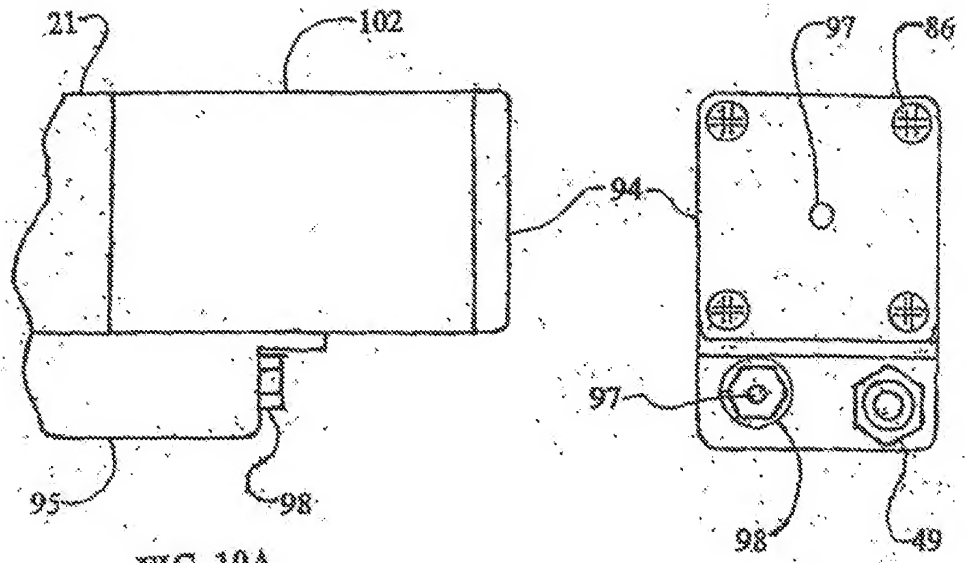

FIG. 10A

FIG. 10B

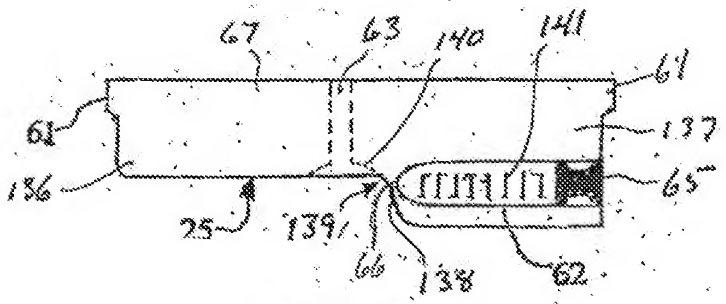

FIG. 11

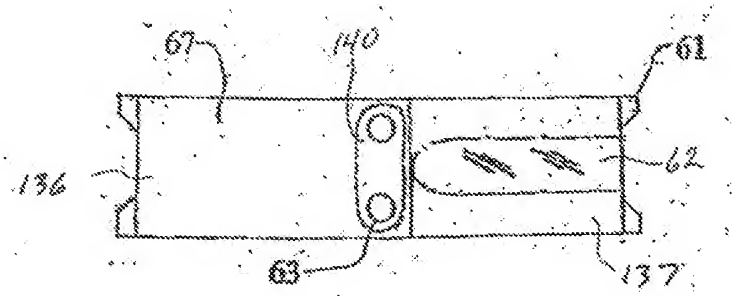

FIG. 12

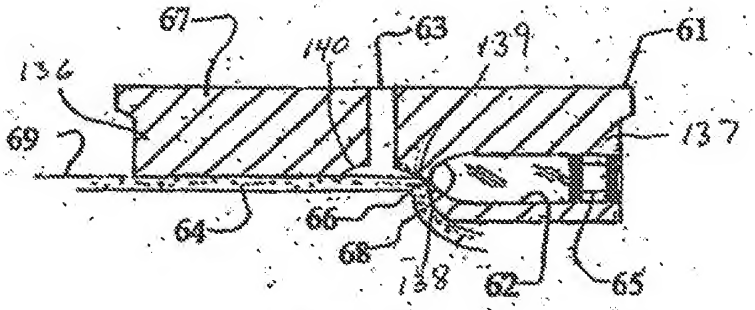

FIG. 13

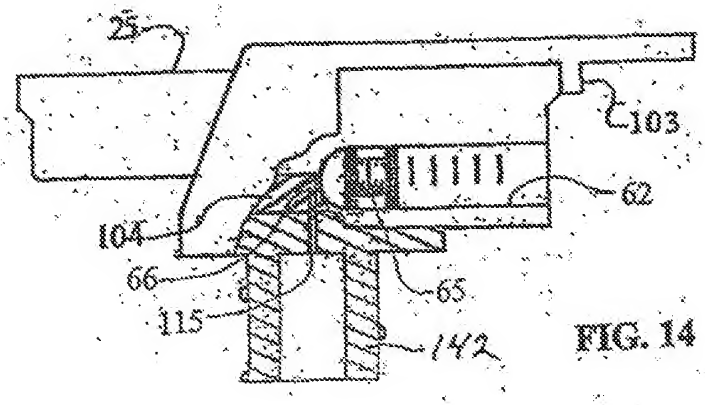

FIG. 14

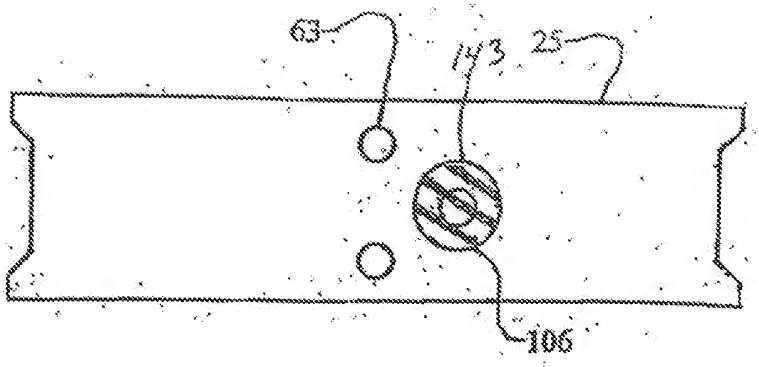

FIG. 15

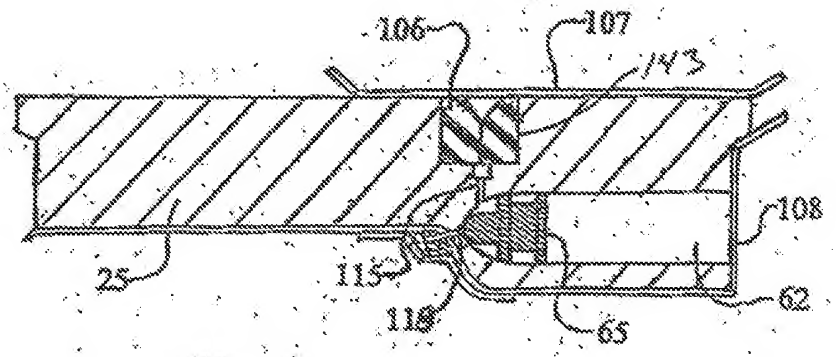

FIG. 16

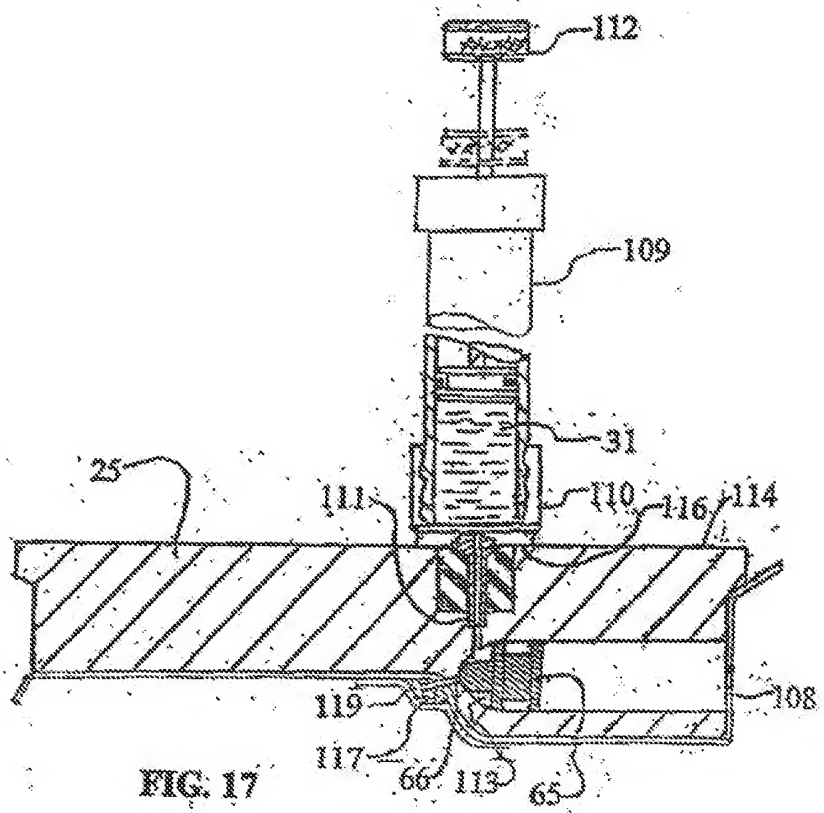
112
109
31
25
111
110
116
114
108
119
117
66
113
65

FIG. 17

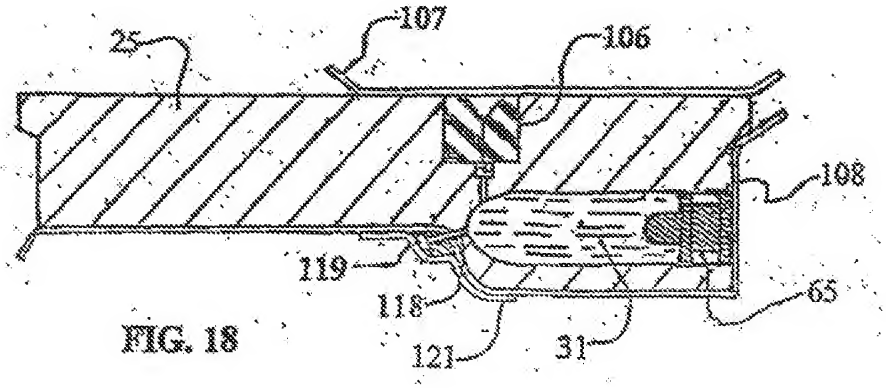
107
106
25
108
119
118
121
31
65

FIG. 18

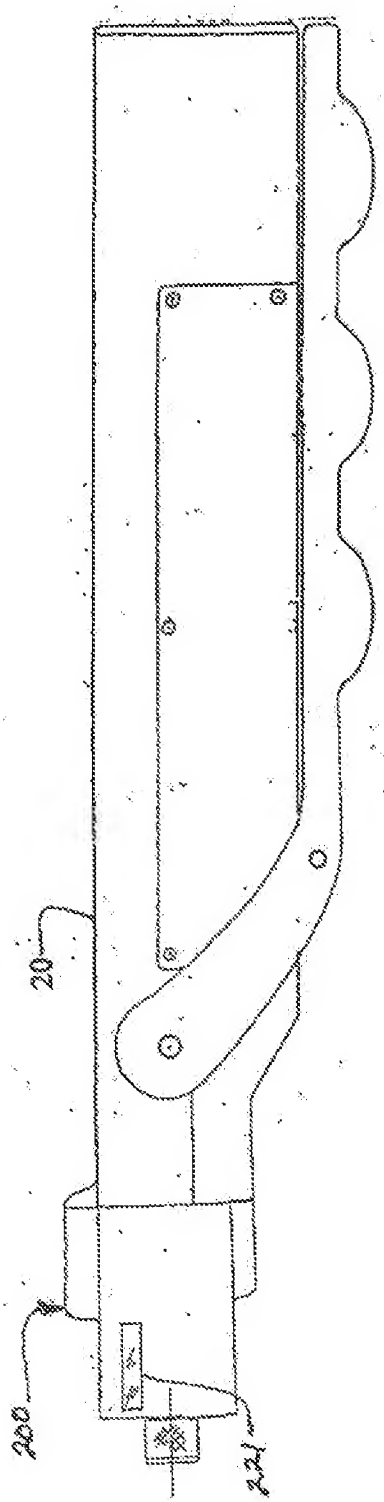

FIG. 19

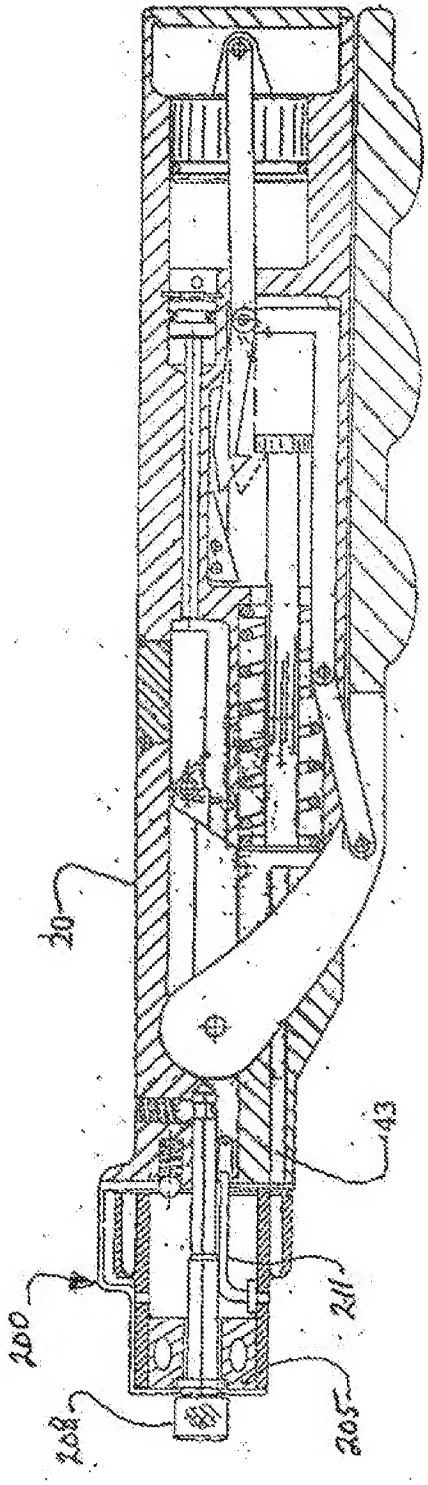

FIG. 20

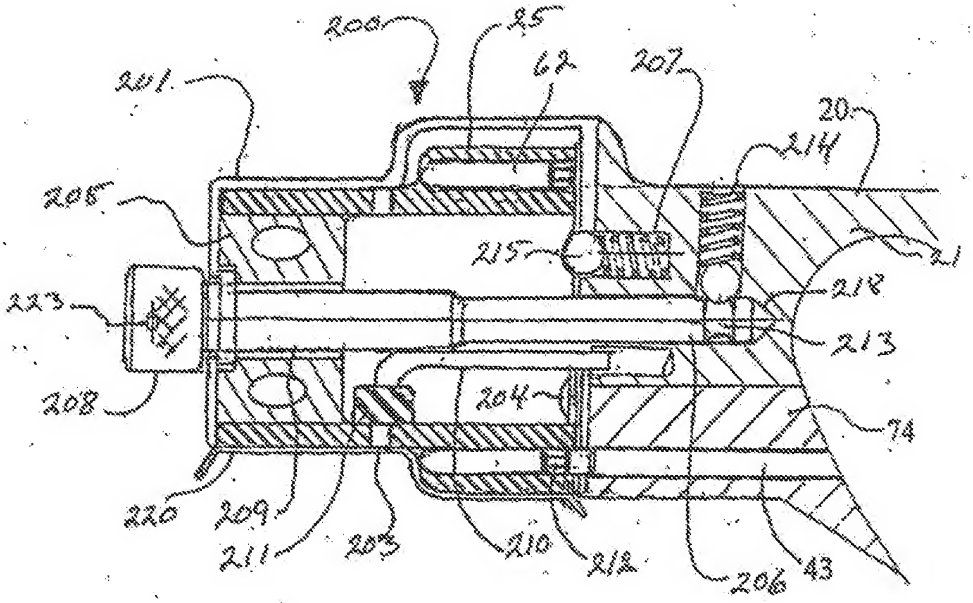

FIG. 21

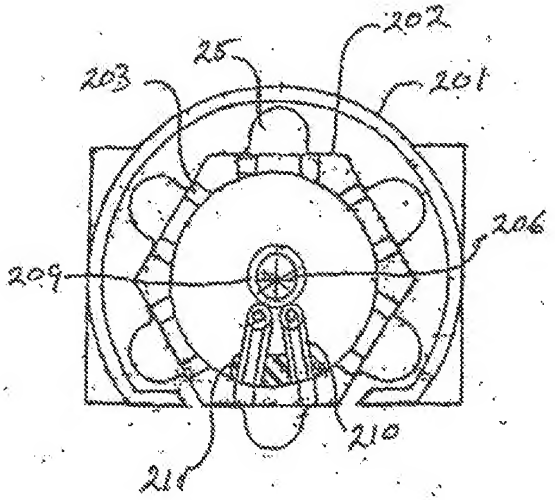

FIG. 22

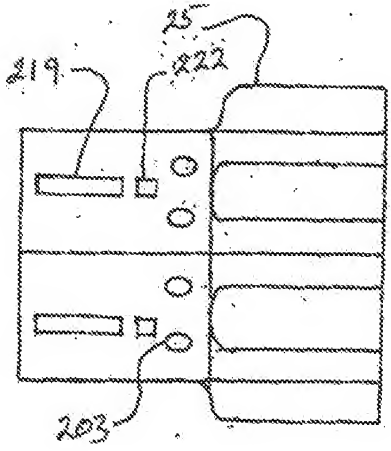

FIG. 23

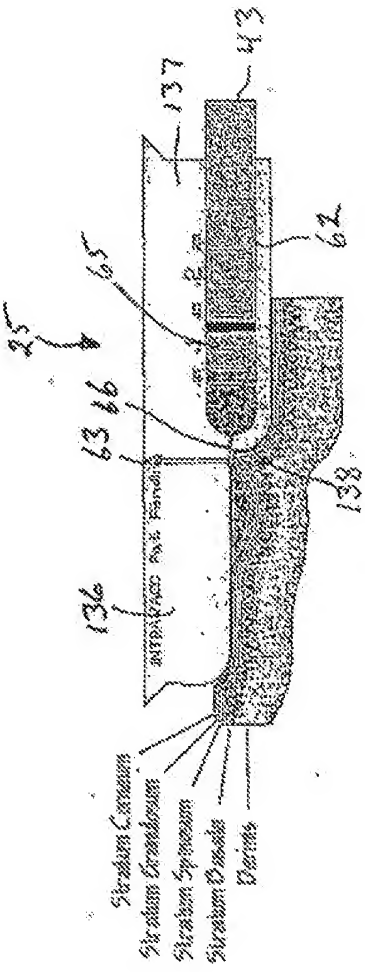
25
63
66
65
137
43
62
136
138
Stratum Corneum
Stratum Granulosum
Stratum Spinosum
Stratum Basale
Dermis

FIG. 24

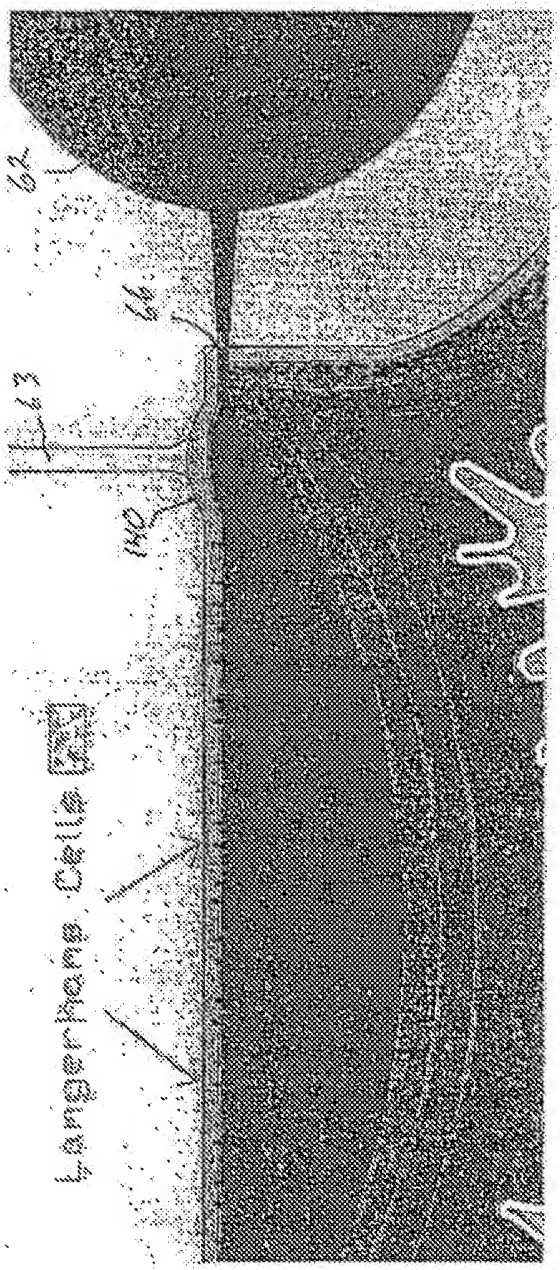
62
64
63
140
Langerhans Cells (LC)

FIG. 25

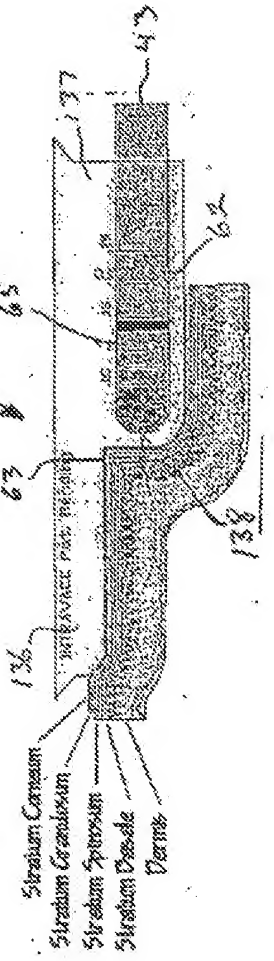
Stratum Corneum
Stratum Granulosum
Stratum Spinosum
Stratum Basale
Dermis
63
65
62
43
177
138
136

FIG. 26

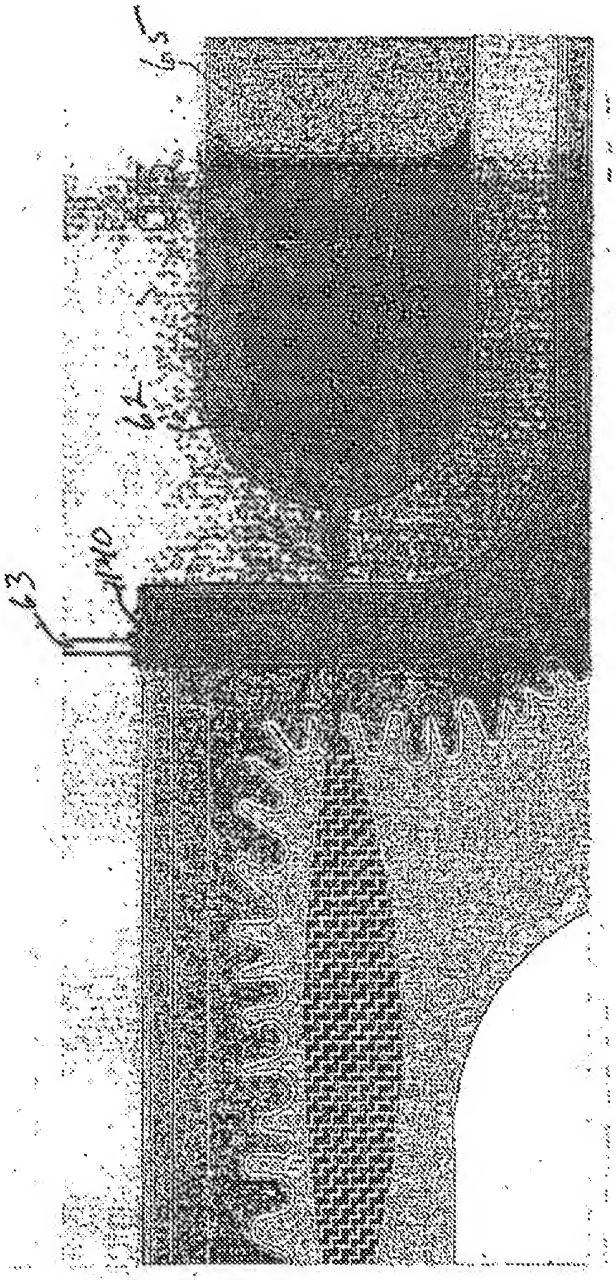
63
140
64
65

FIG. 27